Salama

Central Purchasing of Essential Medicines
and Medical Equipment from Madagascar

FILE OF INTERNATIONAL CALL FOR TENDERS
AOI 1/25

Reference: **AOI 1/25**

Object: Supply in six (6) divisible lots of:

- **Lot No. 1: Essential medicines**
- **Lot No. 2: Medical consumables**
- **Lot No. 3: Dental products**
- **Lot No. 4: Hemodialysis consumables**
- **Lot No. 5: Anticancer drugs**
- **Lot No. 6: New products**

Funding: Equity

February 2025

WARNING

This document has a contractual scope. It specifies the conditions for the execution of the supply services. Candidates must adhere to this document and may not modify it under any circumstances.

Antananarivo February 17, 2024

LETTER OF INVITATION TO TENDER

Object: Supply and prequalification of suppliers (product/manufacturer pairs) of inputs in six (6) divisible lots of:

- **Lot No. 1: Essential medicines**
- **Lot No. 2: Medical consumables**
- **Lot No. 3: Dental products**
- **Lot No. 4: hemodialysis consumables**
- **Lot No. 5: Anticancer drugs**
- **Lot No. 6: New products**

The SALAMA purchasing center hereby invites you to submit your best offer for the products listed above;

Below you will find the means of submission:

FINANCIAL OFFERS	TECHNICAL AND ADMINISTRATIVE FILES	SAMPLES (unregistered and/or non-prequalified product cases)
Email: aoi2025@salama.mg Or Physical version at SALAMA address	- On a storage device (USB or CD) containing the electronic version (accepted formats: .doc; .xls; .pdf; .jpeg; .tiff) of the technical file and the list of supplies to which the candidate has submitted a tender - On an electronic link to an online file sending platform (Google Drive only), the link of which must be valid (Links with limited validity are not accepted, e.g. wetransfer, etc.)	Physical version at SALAMA address

The final submission date will be on **Tuesday April 29, 2025** at **8:00a.m., local time of Madagascar.**

Offers must contain:

1- The financial offer including:

- ✓ Commitment document, signed and/or sealed by the signatory (model of the document to be completed in appendix no. 1)
- ✓ Quantity and price slip completed
- ✓ Completed technical specifications form

2- **Technical and administrative documents:** only for unregistered and/or non-prequalified products
3- **Samples:** only for unregistered and/or non-prequalified products

Information sessions will be scheduled for all suppliers, in person at SALAMA headquarters or by Zoom video conference.

The links will be sent to you 48 hours before each session.

Your presence is strongly recommended for better support in your submission.

The opening of the bids will take place in public session and only in person at the same address on Wednesday, April 30, 2025 at 9:00 a.m. Representatives who wish to attend must bring the letter of representation in Appendix 7, signed and stamped by the signatory of the Company.

Each supplier is requested to acknowledge receipt of this International Call for Tender Document, at the email address info.aoi25@salama.mg

SALAMA looks forward to receiving your offer and thanks you in advance for your interest in our call for tenders.

Mieja Vola RAKOTONARIVO
GENERAL MANAGER

CONDITIONS OF ELIGIBILITY FOR SUBMISSION

1- Inadmissibility of offers:

The following reasons result in the rejection of the bidder's offer:

- Receipt of the offer after the submission deadline date and time
- Non-existence of the commitment document, signed and/or sealed by the signatory
- Non-existence of the completed quantity and price slip
- Non-existence of the completed technical specifications slip

2- Technical eligibility conditions :

- ✓ For medicines registered in Madagascar and prequalified: the reference of the AMM must be entered in the technical specifications slip,
- ✓ For drugs not registered in Madagascar and prequalified, the registration file in CTD format and the samples must be provided at the time of submission,
- ✓ For prequalified consumables, no document is required.
- ✓ For medicines or consumables not prequalified and not registered in Madagascar, the following documents are mandatory when evaluating offers:

2.1. *Administrative part (relating to the bidder)) :*

- Practice authorization issued by the Ministry of Health
- Certified copy of the Tax Registration Card (CIF) 2023 or 2024 or equivalent document.
- A certified copy of the commercial register entry identifying the bidder's main activity.

2.2. Technical part:

For Medicines and Contrast media used in imaging:

- Technical information sheet on the Medicine duly signed and stamped (Mandatory)
- Manufacturers Technical Information Sheet. Mandatory
- The registration application file in CTD format.

For dental products, medical devices, hemodialysis consumables:

- Technical information sheet on supplies other than medicines duly signed and sealed
- Certificate of Good Manufacturing Practices (GMP)
- CE or ISO 9000 certification of each production and distribution site of supplies.
- Certificate of analysis of finished product or certificate of conformity

For laboratory reagents and consumables:

- Technical information sheet on supplies other than medicines duly signed and sealed
- Certificate of Good Manufacturing Practices (GMP)

- Technical data sheet from the manufacturer
- CE or ISO 13485 certification of each production and distribution site of supplies.
- Certificate of conformity

2.3. Samples

The quantity of samples to be provided is 3 sales models for non-prequalified drugs, prequalified but unregistered drugs and non-prequalified consumables.
No samples are required for prequalified consumables or registered or pending registration medicinal products.

3- <u>Evaluation and award criteria for offers:</u>

- Quality according to assessment for prequalification and registration
- Price, based on maximum target price
- Remaining product life upon arrival at SALAMA warehouse: greater than ¾ of total life
- Delivery time not exceeding the 4 to 5 months required

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PART ONE: TENDER PROCEDURE

Instructions to Bidders (IS)

1. Submission

1.1. Means of submission

FINANCIAL OFFERS	TECHNICAL AND ADMINISTRATIVE FILES	SAMPLES (unregistered and/or non-prequalified product cases)
By Email to: **aoi2025@salama.mg** Or In physical version at SALAMA address	- On a storage device (USB or CD) containing the electronic version (accepted formats: .doc; .xls; .pdf; .jpeg; .tiff) of the technical file and the list of supplies to which the candidate has submitted a tender - On an electronic link to an online file sending platform (Google Drive only), the link of which must be valid (Links with limited validity are not accepted, e.g. wetransfer, etc.)	In physical version at SALAMA address

In the case of submission by both email and physical:

- The date and time of receipt considered by SALAMA will be that of the complete and compliant offer received in 1st
- In case of inconsistency between the digital and physical version: the original physical version will be considered

1.2. Composition of the offer:

Offers must contain:

- The financial offer: for all products submitted
- Technical and administrative documents: only for unregistered and/or non-prequalified products
- Samples: only for unregistered and/or non-prequalified products

1.2.1. FINANCIAL OFFERS :

✓ Commitment document, signed and/or sealed by the signatory (model of the document to be completed in appendix no. 1)
✓ Quantity and price slip completed
✓ Completed technical specifications form

1.2.2. TECHNICAL AND ADMINISTRATIVE DOCUMENTS:

See page 4

1.2.3. SAMPLES:

See page 5

➔ Bidders shall place their bids in inner envelopes. These inner envelopes must bear the name and address of the Bidder so as to enable the Purchaser to return the sealed bid if it has been declared “late”.

➔ These envelopes will then be placed in a large sealed outer envelope:

(a) addressed to the Buyer;

(b) will bear the name of the market, the title and the number 'International Call for Tenders' and the words 'DO NOT OPEN UNTIL' followed by the date and time indicated in the invitation to tender letter.

In the event of forgetting this mention, SALAMA will not be held responsible for the consequences due to the accidental opening of the mail due to lack of exact identification of the object of the closed envelope.

If the outer envelope is not sealed and marked as indicated in the above paragraph, the Buyer will not be liable in any way for the offer being misplaced or opened prematurely.

- ➔ **The original and the copy of the offer will be bound or stapled, typewritten or written in indelible ink;**
- ➔ **Any addition between the lines, deletion or overwriting, to be valid, must be signed or initialed by the signatory.**

Bidders must provide any documents that SALAMA may reasonably request establishing to SALAMA's satisfaction that they continue to be eligible to compete.

SALAMA cannot be held responsible for the integrity of the International Call for Tender Documents and its additions, if they have not been obtained directly from it and from an agent authorized by it.

The bidder is required to examine the instructions, models, conditions, forms and specifications contained in the International Tender Documents, he is the guarantor of the quality of the information requested by the International Tender Documents and of the preparation of a bid that complies in all respects with the requirements of the International Tender Documents. Any deficiency may result in the rejection of his bid.

2. Addenda to the International Call for Tenders Document

SALAMA may, at any time before the deadline for submission of tenders, modify the International Call for Tender documents by publishing an addendum.

Any addendum thus published shall form an integral part of the International Tender Document and shall be communicated in writing to all those who have obtained the International Tender Document.

In order to give bidders a reasonable period of time to take the addendum into consideration when preparing their bids, SALAMA may extend the deadline for submitting bids.

The Buyer may, at its discretion, extend the deadline for the submission of bids by publishing an addendum. In such case, all rights and obligations of the Buyer and bidders previously governed by the initial deadline shall be governed by the new deadline.

a. **Submission**

- ✓ The bidder shall bear all costs relating to the preparation and presentation of its bid and SALAMA is in no way responsible for these costs, nor required to pay them, whatever the progress and outcome of the International Call for Tender procedure.
- ✓ Authorized to bid: manufacturers, distributors of local or international pharmaceutical products. For suppliers or manufacturers based outside Madagascar, the presence of local representatives is not required.
- ✓ The tender and all correspondence and documents relating to the tender shall be drawn up in French and/or English. Additional documents and printed matter provided by the tenderer may be drawn up in another language provided that they are accompanied by a translation into French or English of the relevant passages relating to the tender, in which case, for the purposes of interpreting the tender, the French translation shall prevail.
- ✓ Prices will be quoted in accordance with the Price Schedule included in the Tender Forms.
- ✓ Prices will be quoted in local currency (MGA) for local bidders, EURO or US DOLLARS for foreign bidders.
- ✓ The exchange rate to be applied when opening the offer is the sale rate in effect on the day the offer is opened as specified in the Special Data of the International Call for Tender.

b. Clarifications

- A Bidder wishing to obtain clarifications on the documents may make a request in writing to SALAMA no later than seven days (07d) before the deadline for submission of bids, as specified in the Special Data of the International Call for Tenders.
- All requests for clarification should be sent to the email address info.aoi25@salama.mg
- To facilitate the examination, evaluation, comparison of offers and verification of the qualifications of bidders, SALAMA shall have the discretion to request from a bidder clarification of its offer. No clarification provided by a bidder other than in response to a request from SALAMA will be considered. SALAMA's request for clarification, as well as the response provided, will be in writing. No price modification or substantial change in the offer will be requested, offered or permitted, except to confirm the correction of arithmetical errors discovered by SALAMA during the evaluation of offers.

3. Conflicts of interest, fraud and corruption:

✓ A bidder may not be in a situation of conflict of interest. Any bidder found to be in a situation of conflict of interest shall not be admitted to compete for the award of the Contract. A bidder (including all members of a joint venture and all subcontractors of the bidder) may be found to be in a situation of conflict of interest if it is associated or has been associated in the past with a company (or affiliates of a company) that has provided consulting services for the preparation of specifications, plans, calculations and other documents used inthe framework of the contracts awarded under this International Call for Tender.

Fraud and corruption are defined as any bidder:

✓ Engaging in “fraudulent maneuvers” means anyone who distorts or misrepresents facts in order to influence the award or execution of a contract.
✓ Making an attempt to influence SALAMA when examining, evaluating, comparing offers and verifying the capacity of candidates or when making the award decision
✓ Guilty of “corruption” is anyone who offers, gives, solicits or accepts any advantage with a view to influencing the action of an agent during the award or execution of a contract.
✓ Colluding with other bidders (from the same or different group) to influence the price of the products offered beyond competitive levels
✓ In collusion with any person involved directly or indirectly in the context of this call for tender in order to obtain information that could influence their offers
✓ Making "collusive practices": any form of agreement between two or more bidders (whether or not SALAMA is aware of it) aimed at artificially maintaining the prices of the bids at levels which do not correspond to those which would result from the play of competition
✓ Engaging in “coercive practices”: any form of harm to people or their property or threats against them in order to influence their actions during the award or execution of a contract

If such cases arise, SALAMA, following its own investigations and conclusions, will strictly apply its procedures and:

✓ Will reject the bidder's proposal if the case arises before the awards.
✓ Will declare a firm ineligible, either indefinitely or for a period determined by SALAMA. In this case, the firm is prohibited from participating in SALAMA markets for a specified period.
✓ Will cancel the award and the contract, if the contract has been awarded

SALAMA declares that the negotiation, award and execution of the Contract has not given, does not give or will not give rise to acts of corruption within the meaning of the OECD Convention of December 17, 1997 on the fight against bribery of international public officials.

SALAMA shall have the right to include in contracts a provision requiring bidders, suppliers and companies to authorize SALAMA to inspect their accounts and records relating to the performance of the contract and to have them audited by auditors appointed by SALAMA.

SALAMA will have the right to request a visit from the bidder or successful bidder to their premises and warehouses.

4. Guarantee and validity of offers:

a. Offer guarantee or bid bond

In the context of this International Call for Tender, the offer guarantee or bid bond is not applicable.

b. **Performance guarantee**

Within thirty (30) days from the date of receipt of the Buyer's notification of the award of the contract by email, the successful Bidder shall provide the performance security, in accordance with the Administrative Clauses, using the performance security template included in the International Tender Documents (see the template included in this document) or another template acceptable to the Buyer or bank check.

Failure of the successful Bidder to comply with the provisions of the above Clause shall constitute sufficient grounds for cancellation of the award of the contract, in which case the Purchaser may award the contract to the Bidder whose offer is now the second lowest evaluated offer; it may also proceed to launch a consultation and/or call for tenders.

5. Validity period of offers

The offers will be valid for a minimum period mentioned in the Special Data of the International Call for Tender, i.e. until December 31, 2025, therefore for all awards notified in 2025.
The prices in the offer must be firm and not revisable during the validity period of the offer. Any price increase, regardless of the reasons, will result in the cancellation of the contract and the supplier will be evaluated accordingly. SALAMA has the right to blacklist this supplier for a product or for all future collaborations with SALAMA.
The prices in the offer are valid for any allocation notified by email within the period of its validity.
In exceptional circumstances, the Buyer may request the Bidder's consent to an extension of the validity period. The request and the responses to it will be made in writing or by e-mail. The validity of the bid security provided for in this clause will also be extended as long as necessary. A Bidder may refuse to extend the validity of its bid without losing its bid security.

6. Bidders' Alternative Proposals

Unless otherwise provided in the International Call for Tender Particulars, alternative offers will not be accepted.

7. Modification and withdrawal of offers

- The Bidder may modify or withdraw its bid after it has been submitted, provided that written notification of the modification or withdrawal is received by the Purchaser before the end of the period prescribed for the submission of bids.
- No offer may be modified after the deadline for submission of offers.
- No bid may be withdrawn during the period between the deadline for submission of bids and the expiry of the period of validity of the bid specified by the Bidder in its submission.

8. Opening and evaluation of offers

- **Opening of bids by the Buyer**

The Buyer will open the bids, including any amendments made, in public session, on the date, at the time and at the address specified in the invitation to tender letter and in the Special Data of the International Call for Tender, or in the event of postponement of the date, that mentioned in the email exchanges or by letter.

Representatives of bidders who wish to attend the bid opening session must bring the letter of representation duly signed and stamped by the signatory (see form in Appendix 8); otherwise, they will not be able to attend the session.
The names of the bidders, the total amount of the bids, the presence of the documents required and payable at the opening as well as any other information that the Buyer, at its discretion, may deem useful to make known, will be announced at the opening. No bid shall be rejected at this time, except for late bids, which will be returned to the bidders.

All pages of each supplier's original offer will be reviewed by the members of the Tender Commission present at the opening session.
SALAMA will establish a summary table of the bid opening session, which will include at least: the name of the bidder and whether there is a withdrawal, replacement of the offer or modification, the total price of the offer, and the existence or absence of the mandatory documents. The representatives of the bidders present will be asked to sign an attendance sheet. A copy of the opening table will be sent by email to all bidders.

- **Non-conformity, errors or omissions**

- If a tender is substantially compliant, SALAMA may tolerate any non-compliance or omission that does not constitute a substantial deviation from the terms of the tender.
- If a bid is substantially compliant, SALAMA may request the Bidder to submit, within a reasonable time, the information or documentation necessary to remedy the non-compliance or non-essential omissions noted in the bid in relation to the requested documentation. Such omission may not, under any circumstances, be linked to any element of the bid price. Any Bidder who does not comply with this request may have its bid rejected.
- If an offer is substantially compliant, SALAMA will correct arithmetic errors on the following basis:
  - If there is a contradiction between the unit price and the total price obtained by multiplying the unit price by the quantities, the unit price will prevail and the total price will be corrected, unless, in SALAMA's opinion, the decimal point of the unit price is clearly misplaced, in which case the total price indicated will prevail and the unit price will be corrected;
  - If the total obtained by adding or subtracting the subtotals is not exact, the subtotals will prevail and the total will be corrected;
  - If there is a contradiction between the price stated in words and in figures, the amount in words shall prevail, unless this amount is linked to an arithmetic error, in which case the amount in figures shall prevail subject to paragraphs (a) and (b) above.
  - If the Bidder having submitted the lowest evaluated bid does not accept the corrections made, its bid will be rejected.

9. Evaluation and comparison of offers

- To evaluate an offer, the Buyer will use the evaluation method, by item according to the precision mentioned in the Specific Data of the International Call for Tender (DPAOI)
- For the purposes of evaluation and comparison, SALAMA will convert all bid prices expressed in various currencies into a single currency, using the rate set by the source specified in the DPAOI, in effect on the date also specified therein.
- No margin of preference will be granted
- SALAMA will compare all substantially compliant offers to determine the lowest evaluated offer.
- The evaluation of an offer by the Buyer will take into account, in addition to the price, the following criteria:
  - Quality according to the assessment for prequalification
  - Compliance with specifications (see specific technical clauses)
  - The total and remaining life of the products upon delivery to the SALAMA warehouse – to be mentioned in the offers. If no mention is made, SALAMA will take into account that the products will be received at our warehouse in Antananarivo, at least with ¾ of the total life of the product and the allocations will comply with it,
  - The proposed delivery time

    Post-verification

    - The Purchaser shall determine whether the Bidder selected for submitting the lowest evaluated compliant bid has the capacity to perform the contract satisfactorily and without incident in past contracts.
    - This determination will take into account the financial, technical and production capabilities of the Bidder and the evaluations and withdrawals or other incidents in the contracts awarded with SALAMA. It will be based on a review of the evidence of the Bidder's qualifications that it has provided, and on any other information that the Purchaser deems necessary and adequate.
    - The Bidder may be awarded the contract only if the answer is affirmative. If the answer is negative, its offer will be rejected and the Purchaser will examine the second lowest evaluated offer; then it will proceed to the same determination of the capacity of this Bidder to perform the contract satisfactorily.

10. Award of contract

➔ **The Buyer will award the contract**Medicines to the successful Bidder, whose offer it has determined is substantially compliant with the provisions of the International Tender Documents, and that it is the lowest evaluated offer, and that the supplier presents the best expiry dates and delivery time complies with the required delivery time not exceeding 5 months from the award date.

➔ In the event that the medicines are not registered with the Madagascar Medicines Agency, the buyer may either:

- Award the contract on condition that the products concerned are registered

- Or reject the first bidder and will consider the second lowest evaluated bid under the same condition.

The Purchaser reserves the right to accept or reject any offer, and to cancel the International Call for Tenders procedure and reject all offers, at any time prior to the award of the contract, without thereby incurring any liability whatsoever to the affected bidder(s).

11. Right to modify quantities

The Purchaser, at the time of award of the contract, reserves the right to increase or decrease the quantity of supplies specified in the Schedule of Quantities, without changing the unit prices or other terms and conditions of the offer and the tender documents.

Without specifying a MOQ (minimum order quantity) in the supplier's offer, the latter is therefore required to execute the contract. Otherwise it will be considered as a withdrawal and taken into account in evaluations and future collaborations.

12. Notification of award of contract and Result

Before the expiry of the period of validity of the offers, SALAMA will notify the successful Bidder, in writing, that its offer has been accepted.

SALAMA will notify all bidders of the prequalification status of each product.

Notification of the award will constitute the formation of the contract, and the delivery deadline is counted from this notification by email,

SALAMA will respond in writing to any bidder who has submitted a written request to SALAMA to obtain information on the result of its bid or the reason(s) for which its bid was not accepted.

13. Signing of the contract

At the same time as notifying the successful Bidder of acceptance of its offer by sending the award letter and slip by email, the Buyer will send the contract by email, including all the provisions agreed between the parties. The supplier must print the contract and the awards in 2 original copies, initialed per page, signed and stamped and send these copies by DHL courier for signature by SALAMA.

The Supplier will have ten (10) days following the date of notification to return the signed contract in scanned version by email to the address l.rakotoarison@salama.mg then send the document in two original copies, accompanied by the Performance Guarantee (See Clause 3.2 below) by express mail within thirty (30) days following notification. The physical version of the contract, after signature by SALAMA, will then be returned to the suppliers by express mail

Special Data for International Call for Tenders (DPAOI)

The following specific data supplement, clarify, or amend the clauses of the Instructions to Bidders (IS). In the event of a conflict, the clauses below shall prevail over those of the IS.

A. INTRODUCTION	
	Title of the International Call for Tender: **Supply in six (06) divisible lots of:** - **Lot No. 1: Essential medicines** - **Lot No. 2: Medical consumables** - **Lot No. 3: Dental products** - **Lot No. 4: hemodialysis consumables** - **Lot No. 5: Anticancer drugs** - **Lot No. 6: New products** Identification number of the International Call for Tender:**AOI 1/25**
	Name of the Buyer "SALAMA Central Purchasing Agency for Essential Medicines and Medical Equipment of Madagascar"
B. INTERNATIONAL CALL FOR TENDER FILE	
DPAOI1	In order to obtain clarifications or clarifications only, the supplier may send by email to the email address:**info.aoi25@salama.mg**. Clarifications may be requested no later than seven (07) days before the deadline for submission of offers, i.e. before the Tuesday April 22, 2025. Responses to his requests for clarification must be sent no later than 'Friday April 25, 2025. Information sessions will be scheduled for all suppliers, in person at SALAMA headquarters or by Zoom video conference. The links will be sent to you 48 hours before each session.
C. PREPARATION OF OFFERS	
DPAOI2	All documents relating to the submission must be written in French or English,
DPAOI3	The offer submitted by the Bidder must be bound or stapled and shall include the following documents, duly completed: **3.1. The** documents required for acceptance of offers when opening bids: (a) Commitment document signed and/or sealed by the signatory (model of the document to be completed in appendix no. 1) (b) Quantity and price slip completed (c) Completed technical specifications form **3.2. Mandatory documents for the evaluation of offers**: (a) Quantity and price schedule (b) Prequalification documents and samples according to product situation
DPAOI4	4.1. The absence of the signed and/or sealed commitment document, the quantity and price schedule and the technical specifications schedule will result in the rejection of the offer. 4.2. The Bidder must also indicate in the Letter of Submission the delivery time it proposes. (production time + delivery time until delivery to the SALAMA warehouse) The delivery time after the Contract Award=Order Confirmation=Purchase Order is maximum: **04 (FOUR) to 05 (FIVE) MONTHS for all suppliers**

<table>
<tr><td></td><td>Delivery of short-life products will be split: Total lifespan less than 24 months: in two deliveries if necessary,

4.3 Offers must be stapled or bound if physically delivered.</td></tr>
<tr><td>DPAOI5</td><td>Product prices must be:
DDP Salama Antananarivo Madagascar VAT included for all Suppliers
This Incoterm designates the maximum obligation of the Seller, who bears all costs and means relating to shipping, customs clearance, and delivery to the SALAMA warehouse (Duties and Taxes payable, as well as payment of the costs of the handlers who ensure unloading, etc.)

The prices offered by the Bidder will be firm prices for the entire duration of the contract.</td></tr>
<tr><td>DPAOI6</td><td>The Bidder is required to express in ARIARY, or in EURO or in US DOLLARS, all prices

The total amount of the offer according to the supplier's submission currency which must be indicated in the commitment document.

The currency used to convert into a single currency all the prices of the offers expressed in various currencies for the evaluation and comparison of these offers is: the ARIARY (MGA)

The source of the exchange rate to be used is that of the Central Bank of Madagascar. The exchange rate to be applied when opening the offer is the sale rate in effect on the same day as the opening of the offers, i.e. the 'Wednesday April 30, 2025 at 9:00a.m.</td></tr>
<tr><td>DPAOI7</td><td>A Bid Security or Bid Bond is NOT APPLICABLE AND IS NOT MANDATORY</td></tr>
<tr><td>DPAOI8</td><td>Offers will be valid for all awards notified until December 31, 2025.

Therefore, no changes to the price or technical specifications of the offers will be accepted.</td></tr>
<tr><td>DPAOI9</td><td>Alternative offers will not be accepted.</td></tr>
<tr><td>DPAOI10</td><td>In addition to the original of the offer, the number of copies requested is: 01 (ONE)</td></tr>
<tr><td colspan="2">D. SUBMISSION OF OFFERS</td></tr>
<tr><td>DPAOI11</td><td>Suppliers plan to send their offers as follows:

<table>
<tr><th>FINANCIAL OFFERS</th><th>TECHNICAL AND ADMINISTRATIVE FILES</th><th>SAMPLES (unregistered and/or non-prequalified product cases)</th></tr>
<tr><td>By Mail to the address mail:
aoi2025@salama.mg

Or

In physical version at the SALAMA address (see page 4)</td><td>- On a storage device (USB or CD) containing the electronic version (accepted formats: .doc; .xls; .pdf; .jpeg; .tiff) of the technical file and the list of supplies to which the candidate has submitted a tender
- On an electronic link to an online file sending platform (Google Drive only), the link of which must be valid (Links with limited validity are not accepted, e.g. wetransfer, etc.)</td><td>In physical version at the address of SALAMA</td></tr>
</table>
For suppliers wishing to send their offers in physical version and by e-mail, in the event of an inconsistency noted between the two versions, the original physical offer will prevail.</td></tr>
<tr><td>DPAOI12</td><td>For the address for submission of tender documents, refer to Clause 1 of the IS above.

The deadline for submission of offers is as follows:

Date: Tuesday

Hour: 8:00a.m Local times Madagascar</td></tr>
<tr><td>DPAOI13</td><td>The following reasons result in the rejection of the bidder's offer:

➢ Receipt of the offer after the submission deadline date and time</td></tr>
</table>

	➢ Non-existence of the commitment document signed and/or sealed by the signatory ➢ Non-existence of the completed quantity and price slip ➢ Non-existence of the completed technical specifications slip
DPAOI14	The opening of the bids, in public session, will take place at the following address: SALAMA Office Address: Lot III A 112 - Anjanamasina Anosiala - PK 18 RN 4 Ambohidratrimo District 105 ANTANANARIVO MADAGASCAR Date :'Wednesday April 30, 2025 Hour :9:00a.m local times Representatives of bidders who wish to attend the tender opening session must bring the letter of representation (see form in appendix 7).
	E. EVALUATION AND COMPARISON OF OFFERS
DPAOI15	To evaluate an offer, the Buyer will use the item evaluation mode The evaluation will take into account, in addition to the price of the submitted offer, the following criteria: ➢ Quality according to assessment for prequalification and registration ➢ Price, based on maximum target price ➢ Remaining product life upon arrival at SALAMA warehouse: greater than ¾ of total life ➢ Delivery time not exceeding the 4 to 5 months required
	F. AWARD OF CONTRACT
DPAOI16	**SALAMA will award the contract** to the successful Bidder, whose offer it has determined to be substantially in conformity with the provisions of the International Tender Documents, and that it is the lowest evaluated offer.
DPAOI17	The quantities to be allocated may be increased The quantities to be allocated may be reduced (see CCP-4)

PART TWO: WALK

GENERAL ADMINISTRATIVE CLAUSES (CCAG)

This General Administrative Clauses Book (CCAG) is the document applicable to the markets for the supply of pharmaceutical products of the Central Purchasing Office for Essential Medicines and Medical Equipment of Madagascar "SALAMA". It specifies the general conditions

1. DEFINITION

In this International Call for Tenders Document the following terms shall be interpreted as follows:

"Contract" means the agreement between the Contracting Authority and the Contractor, as described and governed in all the documents constituting this file.

“Contractual Documents” means the documents referred to in the contract form, including any amendments to said documents.

"Contract Price" means the contract price payable to the Supplier for the complete and satisfactory performance of the services provided under the contract.

“Products” or “Supplies” means all items which the Supplier is required to deliver to the Buyer in performance of the Contract.

“Services” means, depending on the subject of the contract, supplies of medicines and medical consumables, and/or medical equipment and services.

The Buyer or "SALAMA »designates the Contracting Authority for whose benefit the services provided for under the contract are carried out. It is also the contracting authority.

"Holder" means the bidder or supplier whose offer has been accepted and who concludes the contract with the contracting authority.

"Letter of award» means service order to begin the services and is also valid as “order confirmation” or" Good of order”.

The "Notification" is the action of bringing information or a decision to the attention of the contracting party(ies) by any physical or electronic means enabling the date of its receipt to be determined with certainty. The date of receipt, which may be mentioned on a receipt, is considered to be the date of notification.

“Delivery” means the transfer of ownership of the Supplies from the Supplier to SALAMA, in accordance with the terms stipulated in the Contract.

The "receipt" is the decision, taken after verifications, by which the Buyer acknowledges the conformity of the services with the stipulations of the contract. The decision of receipt is worth attestation of service provided and constitutes the starting point of the warranty periods;

The "admission" is the decision, taken after verifications, by which the contracting authority recognizes conformity, without reservation, services to the stipulations of the contract. The admission decision is worth a certificate of service provided.

The “adjournment” is the decision taken by the contracting authority which considers that the services could be received subject to corrections to be made by the Supplier;

The "rejection" is the decision taken by the Buyer who considers that the services cannot be received, even after adjournment

"Reservations" are all findings of non-compliance with the provisions of the contract, made during the checks prior to admission, which are brought to the attention of the holder and which prevent the awarding authority from issuing the admission decision. In the event of reservations, the admission decision is postponed.

2. CONTRACTUAL DOCUMENTS

Subject to the order of precedence set out in the Contract form, all documents constituting the Contract (and all parts of said documents) are correlative, complementary and mutually explanatory.

These general conditions will apply to the extent that they are not superseded by other contractual provisions contained in the International Call for Tenders Documents.

3. FRAUD AND CORRUPTION

3.1 The Buyer's rule is to ask Bidders and Suppliers to observe, when awarding and executing these contracts, the strictest rules of professional ethics. By virtue of this principle,

The Buyer: Defines, for the purposes of applying this provision, the terms and expressions below as follows:

Any person who offers, gives, solicits or accepts any advantage with a view to influencing the action of a public official during the award or execution of a contract is guilty of “corruption”.

(i) Engages in “fraudulent maneuvers” anyone who distorts or misrepresents facts in order to influence the award or execution of a contract;

(ii) "Collusive practices" means any form of agreement between two or more bidders (whether or not SALAMA is aware of it) aimed at artificially maintaining the prices of bids at levels which do not correspond to those which would result from the play of competition;

(iii) “Coercive practices” means any form of harm to or threats against persons or their property in order to influence their actions during the award or performance of a contract; and;

SALAMA following its own investigations and conclusions, carried out in accordance with its procedures:
(i) Will reject a proposed award if it determines that the proposed awardee is, directly or through an agent, guilty of corruption or has engaged in fraudulent, collusive or coercive practices in connection with the award of this contract;
(ii) Will declare a firm ineligible, either indefinitely or for a specified period, for procurement if, at any time, the firm has engaged in corruption or fraudulent maneuvers, collusive or coercive practices, during the award procedure or the execution of the Contract. In this case, the firm is prohibited from participating in SALAMA procurement for a period determined by SALAMA.

3.2 SALAMA reserves the right, when it has been established by a national or international body that a firm has engaged in corruption or fraud, to declare this firm ineligible, for a given period, for SALAMA markets.

3.3 SALAMA shall have the right to include in contracts a provision requiring bidders, suppliers, contractors, and consultants to permit SALAMA to inspect their accounts and records relating to the performance of the contract and to have them audited by auditors appointed by SALAMA.

3.4 Any communication between the Bidder and SALAMA relating to allegations of fraud or corruption must be in writing.

3.5 SALAMA declares that the negotiation, award and execution of the Contract has not given, does not give or will not give rise to acts of corruption within the meaning of the OECD Convention of December 17, 1997 on the fight against bribery of international public officials.

4. SAMPLES :

- The samples will be provided by the candidate at the same time as its prequalification file, to enable the beneficiary to estimate the conformity of the proposed product to the technical specifications described and its quality. The samples remain the property of"SALAMA »
- The samples will be submitted together with the prequalification file, in separate packaging.
- Samples provided as part of the prequalification file are neither invoiced to the beneficiary nor returned to candidates regardless of the result.
- The samples provided by the candidate will be representative of the quality of the products which will be delivered under subsequent Contracts, for the entire duration of the prequalification.
- The quantity of samples to be provided is 3modelssale
- For a specific type of medical device (offered in different shapes or sizes) the candidate has the option of providing only one of the shapes or sizes.

PRESENTATION OF SAMPLES:

■ The samples will be provided in their original packaging. Their presentation (individual unit packaging and primary packaging, labelling) will be strictly identical to that proposed by the candidate for the services to be provided for subsequent calls for tender. Each sample will bear, in addition to the product labelling, a special sample label, indicating the name of the candidate and the number of the item to which it relates/ matches the sample. This label will be affixed in such a way that the inscriptions and other packaging labels are clearly visible.

■ Deliveries of samples will be accompanied by a delivery note mentioning the brands, references and quantities of the samples supplied. Upon specific request indicated in the table of Technical Specifications of Supplies, the candidate will also produce a complete technical sheet relating to the item concerned.

SAMPLES SHIPPED FROM ABROAD

Envelopes received by SALAMA after the specified deadlines will not be taken into account unless they are international envelopes that were sent no later than 4 days before the deadline for submission of tenders. In this case, the tenderer is required to provide SALAMA with proof of the date on which their envelope was delivered to the international express courier company that they have instructed to deliver it (copy of the international express courier company's collection note). It should be noted that all costs related to delivery from abroad to SALAMA's headquarters are the responsibility of the candidate.

Administrative and technical analysis of prequalification files

The administrative and technical analysis of the prequalification files will be carried out by the Technical Evaluation Committee (TEC) and the Joint Evaluation Committee (JEC) of the offers. This analysis will consist of the following operations, for each prequalification file:

* Review of administrative documents provided as part of the prequalification file.
* Review of technical documents provided as part of the prequalification file
* The absence or non-compliance of one of the documents cited below will result in the elimination of the candidate or the manufacturer who mandated them, as the case may be.
    - The authorization exercise
    - The BPF or GMP of the manufacturing sites of the proposed drugs
    - The ISO or CE certificates for device manufacturers
    - The Letter of approval or trading certificate (Manufacturer's Authorization) for wholesalers.
* Thorough review of the Technical Information Sheet on the products and the manufacturer. The information provided must be consistent with the samples.
* Examination and testing of samples provided.

Only samples from manufacturers whose administrative and technical documents have been provided will be analyzed. The absence of a sample results in the rejection of the product except for narcotic and psychotropic products.

In order to facilitate the examination of the files and the evaluation of the information and documents provided, the Committee will have full latitude to ask the candidate to provide clarifications on his offer. The request for clarification will be made in writing. The candidate's response will be made according to the same provisions, within the time limits and by the means indicated in his request by the Committee.

The administrative and technical analysis of the prequalification files will be concluded, for each file, by the approval or rejection of the product-manufacturer pair.

SUPPLIER APPROVAL

The “SALAMA” Tender Commission will, at the end of the discussions, decide whether to approve or reject the candidate for each prequalification file. These conclusions will be the subject of a report by the Tender Commission.

“SALAMA” reserves the right to carry out or have carried out an audit of the manufacturing sites of prequalified suppliers.

5. INTERPRETATION

A. Incoterms

a. Unless otherwise specified in the CCAP, the meaning of the commercial terms and the rights and obligations assumed by the parties are those prescribed by Incoterms 2010.

b. DDP and other similar terms shall be governed by the rules prescribed in the latest edition of Incoterms published by the International Chamber of Commerce at the date of the invitation to tender.

B. Entirety of the agreements

The Contract represents the entirety of the contractual provisions agreed upon by SALAMA and the Supplier relating to its subject matter, and it supersedes all communications, negotiations and agreements (whether written or oral) entered into between the parties relating to its subject matter prior to the date of the Contract.

C. Amendments

Amendments and other modifications to the contract may only come into force if they are made in writing, dated, if they expressly refer to the contract and are signed by a duly authorized representative of each of the parties to the contract.

6. MARKET LANGUAGE

The offer and all correspondence and documents relating to the submission, exchanged between the Bidder and the Buyer, will be written in French or English.

7. NOTIFICATION

Any notice given to either party by the other party under the Contract must be in writing to the address specified in the CCAP. The expression “in writing” means sent in writing with acknowledgement of receipt.

A notice takes effect on the date on which it is delivered or on the date on which it becomes effective, whichever is the later.

8. SIGNATURE OF THE CONTRACT

- ✓ At the same time as notifying the successful Bidder of the acceptance of its offer, the Buyer will send it the model Contract appearing in the International Tender Documents, by e-mail, including all the provisions agreed between the parties.
- ✓ Within ten (10) days of the notification date, the successful Bidder shall sign and date the Contract and return the scanned version to the Buyer by email; then send the document in two copies (one original and one copy), accompanied by the Performance Guarantee (See Clause 18 below) by express mail within thirty (30) days of the notification.

The physical version of the contract, after signature by SALAMA, will then be returned to the suppliers by express mail.

9. APPLICABLE LAW

The Contract is governed by and interpreted in accordance with the law of the country of the Buyer “SALAMA”.

10. DISPUTE RESOLUTION

- ✓ “SALAMA” and the Supplier will make all necessary efforts to settle, amicably, by direct and informal negotiation, any disagreements or disputes arising between them under the Contract.
- ✓ If thirty days after the start of negotiations for an amicable settlement, “SALAMA” and the Supplier have been unable to settle a dispute arising from the Contract, each party may request that the settlement of the dispute be subject to the procedures specified in the Special Clauses. These procedures may include, but are not limited to, conciliation in the form of mediation by a third party, referral for judgment to a national or international court and/or international arbitration. The method of recourse chosen will be specified in the Special Clauses.

11. SUBJECT OF THE CONTRACT

The Market covers the Supply in six (06) divisible lots of:

- **Lot No. 1: Essential medicines**
- **Lot No. 2: Medical consumables**
- **Lot No. 3: Dental products**
- **Lot No. 4: hemodialysis consumables**
- **Lot No. 5: Anticancer drugs**
- **Lot No. 6: New products**

12. DELIVERY

Delivery of the Supplies and completion of the Related Services will be made in accordance with the delivery and completion schedule set out in the Delivery Schedule, which will set out the details of the shipment and specify the other documents to be presented by the Supplier.

Early deliveries will be accepted, subject to:

- SALAMA's acceptance of early delivery, acceptance materialized in writing (email or letter)
- That payment of the related invoices only occurs 60 days after the delivery date.

13. SUPPLIER RESPONSIBILITY

The Supplier shall provide all Supplies and related services included in the subject of the Contract and the delivery schedule while taking into account the delivery time and the incoterm mentioned in the award note.

For the execution of the contracts, the supplier must strictly follow the steps mentioned in the “CONDITIONS OF EXECUTION OF THE CONTRACT”, p.4

Any shipment, whether at room temperature or under cold chain, must be subject to temperature monitoring using a thermometer which records the temperature data of the data loger type shipment.

14. SALAMA'S RESPONSIBILITY

- ✓ Whenever the Supplier is required to obtain a permit, approval and import or other license from the public authorities of SALAMA's country to supply the Supplies and Related Services, if requested by the Supplier, SALAMA shall use its best efforts to assist the Supplier in complying with such permits, approvals and import or other licenses in a timely and expeditious manner.
- ✓ "SALAMA" shall pay all costs attributable to the performance of its responsibilities, in accordance with clause 13.1 above.
- ✓ "SALAMA" will share the list of cold chain products as well as the technical specifications of the types of monitors.

15. QUALITY GUARANTEES

- ✓ The Supplier warrants the quality of all Supplies delivered in performance of the Contract. The Supplier further warrants that the Supplies delivered in performance of the Contract will not have any defects due to their manufacture, the raw materials used or their use, or to any act or omission of the Supplier, occurring during the normal use of the Supplies delivered under the conditions prevailing in the country of final destination.
- ✓ This warranty will remain valid until the expiration date of the products.
- ✓ "SALAMA" will notify the Supplier in writing of any claim involving this guarantee.
- ✓ Upon receipt of such notification, the Supplier will, within a maximum period of 30 (thirty) days, repair or replace the defective supplies or their parts, at no cost to "SALAMA".
- ✓ If the Supplier, after notification, fails to rectify the defect(s) within the required time period, "SALAMA" may begin to take the necessary measures, at the Supplier's risk and expense and without prejudice to any recourse by the Supplier against "SALAMA" under the terms of the contract.
- ✓ Products under cold chain must comply with the conditions mentioned in clause 21 of the CCAG. The supplier is responsible for maintaining the cold chain up to the agreed delivery point according to the incoterm, by deploying the equipment adapted for this purpose. In the event of non-compliance, SALAMA reserves the right to refuse receipt (according to the level of risk per product, e.g. insulin,)
- ✓ The prices that the Supplier will charge for the Supplies delivered and the services rendered in execution of the contract will not vary from the prices indicated in its offer.

16. MARKET PRICE

The prices that the Supplier will charge for the Supplies delivered and the services rendered in execution of the contract will not vary from the prices indicated in its offer.

17. SUPPLIER DELAY

- ✓ The delivery of supplies and the execution of services will be carried out by the Supplier in accordance with the schedule specified by "SALAMA" in the special clauses.
- ✓ Any delay by the Supplier in fulfilling its delivery obligations will expose it to one or all of the following penalties:
  - Termination of the Contract for failure to perform and/or
  - Imposition of penalties ; and/or
  - Seizure of his performance bond
  - Reduction of the allocated quantity

- ✓ If, at any time during the performance of the Contract, the Supplier has circumstances that prevent it from delivering the supplies in a timely manner, the Supplier shall promptly notify “SALAMA” in writing, informing it of the existence of the delay, its probable duration and its cause(s). As soon as possible after receipt of the Supplier's notification, “SALAMA” shall assess the situation, it shall have full discretion to extend the delivery or performance deadline, in which case the extension shall be ratified by the parties by amendment to the contract.

18. PAYMENT TERMS

- ✓ The Market price will be settled in accordance with the provisions of the CCAP.
- ✓ The Supplier shall submit the required documents to SALAMA, accompanied by invoices describing, in an appropriate manner, the supplies delivered and the related services rendered, and the exhibits presented, and after having satisfied all the obligations specified in the Contract.
- ✓ Payments due to the Supplier will be made without delay by SALAMA, and at the latest within sixty (60) days following the presentation of the invoice and the documents required by the Supplier, and after its acceptance by SALAMA.
- ✓ The currency(ies) in which payments will be made to the Supplier under the Contract will be the currency(ies) in which the tender price is stated.

19. GUARANTEE OR SECURITY OF GOOD PERFORMANCE

- ✓ Within thirty (30) days of receipt of the award of the Contract, the Supplier shall provide a guarantee for the proper performance of the Contract, for the amount specified in the CCAP.
- ✓ The amount of the guarantee will be payable to SALAMA as compensation for any loss suffered due to the Supplier's failure to perform its contractual obligations.
- ✓ The performance guarantee will be denominated in the currency of the Contract, and presented in the form stipulated in the CCAP or in another form acceptable to SALAMA.
- ✓ The validity of the performance bond is ONE YEAR.
- ✓ SALAMA will release and return to the Supplier the performance guarantee no later than thirty (30) days after the date of performance of the Supplier's obligations under the Contract.

20. CONFIDENTIAL INFORMATION

- ✓ “SALAMA” and the Supplier shall respect the confidential nature of any document, data or other information provided directly or indirectly by the other party under the Contract, and shall not disclose them without the written consent of the other party, whether such information was provided before, during or after the execution or termination of the Contract.
- ✓ “SALAMA” shall not use any documents, data or other information received from the Supplier for purposes other than those of the Contract. Similarly, the Supplier shall not use any documents, data or other information received from SALAMA for purposes other than the acquisitions or other works and services required for the execution of the Contract.
- ✓ The above provisions do not in any way modify a confidentiality undertaking given by either party before the date of the Contract on all or part of the supply.
- ✓ The provisions of clause 19 of the CCAG shall survive the completion or termination of the Contract, regardless of whatever the reason.

21. SUBCONTRACTING

No subcontracting will be authorized under this contract.

22. PACKAGING AND DOCUMENTS

- ✓ The Supplier shall package the Supplies in the manner required to ensure that they do not suffer damage or deterioration during transport to their final destination, in accordance with the provisions of the Contract. During transport, the packaging shall be sufficient to withstand rough handling and extreme temperatures, salt and precipitation, and open-air storage in all circumstances. The dimensions and weight of the crates shall take into account, whenever necessary, the fact that the final destination of the Supplies is remote and the possible absence, at all stages of transport, of heavy handling equipment.
- ✓ The packaging, marking, labelling and documentation inside and outside the crates will strictly comply with the provisions specified in the Contract as well as with subsequent instructions, where applicable, in application of the CCAP, and with any other instructions given by SALAMA.
- ✓ All products, including cold chain products, must be clearly identified by indicating the required temperature on the package/shipping document and have a temperature recording device (such as logtag, sensitech, haier or others).
- ✓ Unless otherwise specified in the CCAP, the supplies delivered in execution of this Contract will be fully insured against any loss or damage arising from their manufacture or acquisition, their transport, their storage and their delivery in accordance with the Incoterms in force or in the manner specified in the CCAP.

23. TRANSPORTATION

Unless otherwise specified in the CCAP, responsibility for the transport of the Supplies is assumed by the party specified in the Incoterms referred to in the Schedule of quantities and delivery schedules.

24. PENALTIES AND SEIZURE OF PERFORMANCE GUARANTEE

Subject to the provisions of clause 10 of the General Clauses, if the Supplier fails to deliver any or all of the Supplies, or to render the services provided for within the time(s) specified in the Contract, "SALAMA", without prejudice to any other remedies it may have under the Contract, may deduct from the price thereof, as penalties, an amount equivalent to that indicated in the General Clauses, calculated pro rata to the value of the supplies suffering the delay for each day of delay before actual delivery, up to a maximum amount of 10% of the price of said Supplies. Once this maximum is reached, "SALAMA" may consider terminating the Contract, and award the Contract to another Supplier.

SALAMA reserves the right to seize the performance bond in the following cases:

- Withdrawal for any reason whatsoever (including price increase, insufficient quantity without mention of MOQ in the initial offer, non-delivery)conform, etc.…)
- In the event that the performance bond has not yet been received by SALAMA, the latter reserves the right to deduct the amount relating to the bond from the current or future invoice(s).

25. TERMINATION AND WITHDRAWAL

- ✓ Termination for Non-Performance and Discontinuance

The “SALAMA” Purchasing Center may, without prejudice to other remedies available to it under the Contract, notify the Supplier of the termination of part or all of the Contract under the following conditions:

(a) if the Supplier fails to deliver any or all of the Goods within the time(s) specified in the Contract;

(b) if the Supplier fails to perform any other of its obligations under the Contract, in particular with regard to the quality of the Goods;

(c) In the event of the occurrence of force majeure events and whenever “SALAMA” considers that the delay risks compromising its activities.

If, after the award, the Holder withdraws and does not deliver one or more products awarded to it, the “SALAMA” Purchasing Center will terminate the contract by simple notice by email.

(d) If the Holder withdraws after signing the contract or during the period of validity of the offers for part or all of the contract, SALAMA will seize its performance bond and it will be suspended during the next Restricted Call for Tenders from “SALAMA” on the products which were the subject of the withdrawal during this Call for Tenders.

- ✓ Termination due to insolvency

“SALAMA” may terminate the Contract at any time by written notice, without prejudice to its rights, if the Holder is declared bankrupt or becomes insolvent.

26. FORCE MAJEURE

- ✓ The term “Force Majeure” means an event beyond the control of the Supplier, which is not attributable to its fault or negligence and which is unforeseeable. Such events may include, but are not limited to, disturbances such as wars, revolutions, quarantine measures and embargoes on freight, disasters or accidents (cyclones, floods, fires, epidemics, ...), acts of terrorism, acts of government, lockouts, changes in market conditions, etc.
- ✓ In the event of Force Majeure, the Supplier shall promptly notify “SALAMA” in writing of the existence of the Force Majeure and its reasons. Unless it receives instructions to the contrary from “SALAMA”, the Supplier shall continue to perform its obligations under the Contract to the extent that it is reasonably possible to perform them, and shall endeavour to find any other reasonable means of performing the obligations the performance of which is not hindered by the Force Majeure.
- ✓ Notwithstanding the provisions of clauses 5, 6 and 7 of the General Clauses, the Supplier shall not be exposed to the seizure of its performance bond, or to penalties, or to termination for non-performance if its delay in performing its services or other failure to fulfill the obligations incumbent upon itin execution of the Contract is due to Force Majeure.

27. SUPPLIER EVALUATION

All facts and actions carried out by the Supplier in the execution of this contract will be evaluated and taken into account in future transactions.

The evaluation criteria are:

- Compliance with delivery deadlines
- Execution of the contract
- Conformity to technical specifications upon delivery
- The existence of quality/salama complaints in relation to the number of batches delivered
- The time limit for responding to complaints on regulatory affairs (registration)
- Compliance following post-marketing quality control

28. REGISTRATION OF MEDICATIONS

- ✓ According to the legislation in force, any medicine dispensed on the territory of Madagascar must have a Marketing Authorization (MA) issued by the Madagascar Medicines Agency. The supplier must be able to present to SALAMA a copy of the MA certificate or any document certifying that the product is accepted by the Madagascar Medicines Agency for sale on the national territory.
- ✓ Any drug prequalified by SALAMA must have a valid marketing authorization at the time of awarding the contracts or, failing that, must have provided all the required documents to SALAMA. A deadline will be given to the supplier to complete all documents.

According to the Letter of Understanding between SALAMA and the Madagascar Medicines Agency relating to the registration of essential medicines entering the SALAMA circuit, the registration application files required by the Registration Service in CTD format (Module 1 to 5) or the files listed below:

- 01 Summary of product characteristics (SPC) with the list and references of active raw materials and excipients with known effects;
- 01 Certified copy of the original (notarized copy) of the Good Manufacturing Practices (GMP) certificate from the manufacturing laboratory established by the competent health authority of the country and valid for at least 6 months;
- 01 Certified copy of the original (notarized copy) of the manufacturer's manufacturing license
- 01 Certified copy of the original (notarized copy) of the marketing authorization for the medicine issued by the competent authorities of the country of origin or, where applicable, the country of provenance;
- 01 Certified copy of the original (notarized copy) of the WHO model certificate of pharmaceutical product (COPP);
- Formulation for a manufacturing batch and for a unit dose
- Information on the origin of the active substance (manufacturer's name, address, contact details and notarized copy of the manufacturer's GMP certificate)
- Certificates of analysis for 3 batches of the active substance provided by the manufacturer of the active substance and 3 batches provided by the manufacturer of the finished product
- Certificates of analysis of excipients
- TSE/BSE declaration certificate (< 3 years) signed and dated for excipients of animal origin from the manufacturer or declaration of absence of excipients of human and/or animal origin for Magnesium Stearate
- Detailed description of the manufacturing process and complete diagram showing the different stages of the process, with critical stages and control points, up to packaging
- For sterile products: complete sterilization process and/or aseptic procedures and their validation
- Certificates of analysis for 3 batches of finished product
- Certificate of analysis corresponding to the batch of the sample provided
- 01 copy of the finished product control methods recommended by the manufacturer with validation in the case of In-House methods.
- 01 stability study protocol
- 01 Complete result of the stability study of the finished product in accelerated and real time.

For laboratories, manufacturers or entities not represented in Madagascar, the supplier will authorize SALAMA by official letter to submit the files to AGMED for registration for the public circuit only (SALAMA circuit) and to follow up until registration is obtained.

- The model samples of sales of medicines required by the registration, with the quantities required by the procedures of the latest edition of the Madagascar Medicines Agency, the quantities to be provided of which are:
    - Tablets and capsules in single-unit packaging (blister, strip): Three (3) secondary packagings (e.g.: box of 100) intact with original label in addition to 100 units
    - Injectable ampoules and vials: Three (3) secondary packaging (e.g. box of 100) intact and duly labeled in addition to:
        - 50 ampoules: solutions and powders for injections
        - 100 vials: solutions or suspensions (<5ml)
        - 50 vials: solutions or suspensions (5ml≤ solution < 50ml)
        - 20 vials: solutions or suspensions (50ml ≤ solution < 100ml)
        - 10 bottles: solutions or suspensions (100ml ≤solution <500ml)
        - 5 vials: solutions ≥500 ml
    - Solutions and ointments for external use: Five (5) units in addition to:
        - 50 tubes: ointment and cream (mass < 5g)
        - 20 tubes: ointment and cream (5g ≤ mass ≤ 15g)
        - 10 tubes: ointment and cream (mass > 15g)

Registration fees :

- Free for cancer patients
- 200 Euros per product. Payment must be made to the bank account of the Madagascar Medicines Agency below, after receipt of an invoice issued by this institution:
    - Madagascar Medicines Agency (EURO)
    - Name of the Bank: MALGACHE BANK OF THE INDIAN OCEAN
    - Account holder: MADAGASCAR MEDICATION AGENCY
    - Account number: 00004 00002 07047620101 03
    - BIC Code: BMOIMGMG
    - IBAN code: MG4600004000020704762010103

All bank charges related to transfers are the responsibility of the supplier.

In order to speed up the registration process, registration fees may be advanced by SALAMA following the supplier's handwritten request, and will be deducted from the final invoice.

In the case of drugs of ICH or Egyptian origin, the registration procedures are governed by the Madagascar Medicines Agency.

✓ In all cases, the beneficiary must ensure that these medicines are registered or, failing that, provide all the documents required for registration in Madagascar at the time of embarkation. No unregistered medicine should be presented at the ports of disembarkation in Madagascar. Beneficiaries are advised that non-compliance with these rules seriously exposes the competent authorities to refusal of customs clearance of the goods. The SALAMA Purchasing Center cannot be held responsible for any damages resulting therefrom.

SPECIAL CLAUSES CCP

A - SPECIAL ADMINISTRATIVE CLAUSES

1. GENERAL INDICATIONS

The following special clauses will supplement the General Clauses. In all cases where the provisions contradict each other, the following provisions will prevail over those of the General Clauses.

2. CONTRACTING AUTHORITY

This International Call for Tender is launched by:

THE CENTRAL PURCHASING CENTRE FOR ESSENTIAL MEDICINES AND MEDICAL EQUIPMENT IN MADAGASCAR, CALLED "SALAMA".

"SALAMA" is a non-profit association, with autonomous management, whose mission is to supply public health structures, as well as private non-profit training, with generic Essential Medicines and Medical Consumables appearing on the latest National List published by the Ministry of Public Health.

"SALAMA"
(Central Purchasing of Essential Medicines and Medical Equipment of Madagascar)
Lot III A 112 - Anjanamasina Anosiala - PK 18 RN 4
District Ambohidratrimo - 105 ANTANANARIVO - MADAGASCAR
Tel: 261 34 97 469 24 / 261 34 13 469 25 - Email: salama@salama.mg

3. SUBJECT OF THE CONTRACT

The Market concerns the**Supply in six (06) divisible lots of:**

- **Lot No. 1: Essential medicines**
- **Lot No. 2: Medical consumables**
- **Lot No. 3: Dental products**
- **Lot No. 4: hemodialysis consumables**
- **Lot No. 5: Anticancer drugs**
- **Lot No. 6: New Products**

The quantity is shown in the quantity and unit price schedule of each supplier within the framework of this International Call for Tender document.

4. DURATION OF THE MARKET

The Market remains valid until delivery of the entire order to the SALAMA warehouse.

During the term of the Contract, “SALAMA” may place firm orders with the successful bidders, within the limits provided for in Article 4 of the Special Administrative Clauses, for the items for which they have been selected, at the tender prices as indicated in their tenders.

5. PRICE SETTING TERMS AND PRICE SYSTEM.

5.1 Bid Price

The unit prices for submission are understood to be: DDP SALAMA ANTANANARIVO MADAGASCAR including VAT for all Suppliers

The Prices are FIRM for the duration of the Contract defined in article 5 of the Special Administrative Clauses.

5.2 Tax regime

In the event of a change in the tax regime and/or tax rates in force in Madagascar, SALAMA reserves the right to renegotiate the Contract price with the Supplier in proportion to the new rates.

6. PERFORMANCE GUARANTEE

- ✓ For each order, within thirty (30) days of receipt of the order award letter issued by "SALAMA", the successful Bidder must provide a Performance Guarantee equivalent to 10% of the total amount of the contract awarded.
- ✓ Bank guarantee for performance for foreign suppliers and bank check for local suppliers;
- ✓ Valid for ONE YEAR, extendable.
- ✓ The Bank of the successful Bidder must be a first-rate bank.
- ✓ This performance bond is mandatory for any contract awarded under this International Call for Tender and will be exempt if the amount of the contract is less than:1500 USD or 1200 EUR for foreign suppliers
- ✓ Or the equivalent in local currency MGA for local suppliers (Exchange rate on the date of order allocation)
- ✓ And will be released no later than 30 (thirty) days after delivery by means of a release certificate issued by SALAMA
- ✓ This deposit will be waived if the delivery time is less than 30 days.
- ✓ In the event of poor performance by the supplier of its contractual obligations under the conditions set out in the general administrative clauses, SALAMA reserves the full right to seize the performance bond and inform the holder at the same time.

7. PAYMENT OF SUPPLIERS

7.1 Payment terms: CHECK for LOCAL SUPPLIERS and WIRE TRANSFER for foreign suppliers

- by bank transfer to a bank located in the country of the foreign Supplier in the submission currency, and upon presentation to SALAMA of the documents indicated in the special administrative clauses for the advance and article 3 paragraph 3.1 of the special technical clauses for the balance.
- by check for local suppliers upon presentation at SALAMA of the documents indicated in the specific administrative clauses.

7.2 Payment terms:

7.2.1 Payment in Advance:

The advance is provided for contracts with an amount greater than: 26,000 USD or 20,000 EUR or 90,000,000 MGA.

The advance rate is set at 30% of the contract amount.

SALAMA reserves the right to make a derogatory decision regarding the granting of an advance

Payment of the advance will be made within thirty (30) days upon presentation at “SALAMA”:

- of the proforma invoice corresponding to the contract;
- a performance bond equivalent to 10% of the contract amount
- a bank guarantee, equivalent to 30% of the contract amount,

Bank guarantee and security deposit for foreign suppliers issued by a first-rate bank, and bank checks for local suppliers with a validity of ONE YEAR, extendable.

Payment of the balance 70% of the contract amount will be made after deduction and/or lifting of any possible reservations, within a maximum period of 60 days after delivery.

For short-lived products, split deliveries, possibility of payment after each delivery.

7.2.2 Payment without Advance:

Payment will be 100% of the contract amount within a maximum period of 60 days against the performance bond and after deduction and/or lifting of any possible reservations.

Possibility of partial payment by invoice after each partial delivery

8. DELIVERY TIME OR EXECUTION TIME

Unless otherwise agreed by “SALAMA”, the actual delivery time of the order must be that mentioned in the allocation slip following the supplier’s offer.

Regardless of the payment terms adopted, the delivery period begins after receipt by the holder of the original letter of allocation = purchase order; justified by a discharge for local suppliers and proof of express mail delivery (tracking on website) for foreign suppliers.

As part of this International Call for Tender, a grace period of 10 days is granted to the successful bidder. After this period, the delivery penalty will be applied.

9. PENALTIES FOR LATE DELIVERY

9.1 When the contractual delivery period is exceeded due to the supplier, the latter will incur, per day of delay and without prior notice,

A penalty calculated according to the following formula:

P= VXR / 1000 in which

- P = Amount of penalties,
- V = Penalized value (supply not delivered)
- R = Number of calendar days late.

✓ The deductible amount will be capped at 10% of the amount of the penalized value

✓ Regardless of late payment penalties, “SALAMA” will have the right to provide the service needs at the supplier’s expense and risk and may terminate the Contract in the event of excessive or repeated delays.

✓ If the supplier has a specific request regarding the late payment penalties applied, it must notify SALAMA by an official letter with the reasons and supporting documents for the request.

✓ SALAMA will evaluate the request and reserves the right not to follow up.

B - SPECIAL TECHNICAL CLAUSES

B.1. TECHNICAL CLAUSES RELATING TO PREQUALIFICATION

ARTICLE 1. Characteristics of the supplies

1.1 Name of Supplies

All supplies must be presented and labeled:

- under their International Common Name (INN) when it comes to essential generic medicines.
- under the name by which they are identified within the framework of this call for tenders (see the table of Technical Specifications of Supplies), for medical-pharmaceutical consumables, medical equipment, laboratory reagents and equipment and dental products.

1.2 Reference pharmacopoeias

The pharmaceutical products delivered will comply with one of the following internationally renowned pharmacopoeias in their latest versions:

- ***British Pharmacopoeia (BP)***
- ***United States Pharmacopoeia (USP)***
- ***European Pharmacopoeia (PhEur)***
- ***International Pharmacopoeia (IP)***
- ***Chinese Pharmacopoeia***

If a delivered pharmaceutical product does not comply with one of these reference pharmacopoeias, the following measures will be taken:

- In his offer, the candidate is required to indicate this and to indicate precisely the reference Pharmacopoeia to which he is referring (e.g.: Inhouse specifications, Indian pharmacopoeia, etc.)
- The Holder must provide the corresponding control protocol or analytical method (Process) and the necessary standard substances.

1.3 Reference standards

Certain specific supplies are described within the framework of international standards systems. The systems chosen as reference within the framework of the Contract are the CE, ISO and AFNOR standards.

The specific areas of application of certain standards are detailed in Article 3 of the Technical Specifications.

1.4 Origin of Supplies

1.4.1 Preliminary definitions

For the purposes of this clause, “origin of the Supplies” means the place where the Supplies are extracted, grown or produced.

Supplies are "produced" when, by manufacturing, processing or significant and essential assembly of components, a product is obtained which is recognised as suitable for marketing, the fundamental characteristics, purpose or utility of which are substantially different from those of its components.

The origin of the supplies is distinct from the nationality of the holder or manufacturer.

1.4.2 Application clauses

The holder is required to deliver, under the Contract, the supplies corresponding to those described in its prequalification file, both in terms of their quality and their origin (manufacturer and country of origin), to the exclusion of any alternative.

The impossibility of satisfying this clause must be duly reported and justified to the Beneficiary as soon as possible.

ARTICLE 2: Packaging

2.1 Packaging specifications and protection

The Supplies and their packaging must have the technical characteristics necessary for their use in the climatic conditions prevailing in Madagascar.

All packaging will be delivered hermetically sealed and will have a closing device to identify any tampering.

The supplier is required to refer to the technical recommendations of the WHO. (WHO Technical Report Series 902, annex 9).

IMPORTANT NOTE: The legal notices on primary packaging (blisters, strips, ampoules, infusion bottles, etc.) must be engraved or printed with indelible ink, therefore not erasable with alcohol.

2.2 Presentation of dry oral forms (tablets and capsules)

Unless otherwise specified for a particular product, tablets and capsules must be presented in unitized packaging. Preference will be given to unitized packaging (blisters or strips) during the price analysis.

2.2.1 Presentation in bulk packaging (exceptional):

In addition to the opaque, hermetically sealed outer packaging fitted with an anti-tamper device, the bulk packaging of tablets and capsules will include the following devices:

- a sealed inner pre-packaging,
- drying devices,
- the padding of the upper part of the packaging.

2.2.2 Presentation in unitized packaging:

Unit packaging will be done according to one of the following options:

- under transparent film;
- under opaque film;
- under plate (blister);
- under plate with individual cells or strip, each cell containing all the information allowing the identification of the product and the batch.
- **It is strongly recommended that the legal notices on the primary packaging (blisters, strips) be engraved. Failing this, they can be printed in indelible, non-erasable ink.**

The option chosen by the candidate and the materials used for the manufacture of the films or plates must guarantee good conservation of the products in the climatic conditions of Madagascar: resistance, depending on the chemical nature of the medicines, to air, humidity, light and heat.

- In order to be able to judge the relevance of its proposals, the candidate will provide all the technical documentation relating to them, as well as the required references (pharmacopoeias, etc.).

2.2.3 Presentation of injectable forms

Unless otherwise indicated for a particular product, injectable solutions will be packaged either in two-point ampoules or in bottle ampoules. Solutions with a volume equal to or greater than 5 ml will be presented in bottle ampoules. Both forms of ampoules accepted will be self-breakable.

Powders for reconstitution of solutions or suspensions for injection will be packaged in individual glass vials with aluminum/plastic Flip-Off caps and seals.

Water for injections will be packaged in semi-rigid plastic bottles equipped with an easy-opening cap.

2.2.4 Presentation of infusion solutions

Unless otherwise indicated for a particular product, infusion solutions will be packaged using one of the following methods:

- either in flexible bags, made of material conforming to the European Pharmacopoeia or in any other complex (formula to be indicated and Pharmacopoeias or Reference Standards to be specified), packaged using a double packaging system;
- either in rigid or semi-rigid plastic bottles, compliant with the European Pharmacopoeia.

The bottle caps must be made of a material that guarantees leak-tightness during use (EURO HEAD). “NIPPLE HEAD” type bottles will not be accepted unless otherwise advised by the technical evaluation committee.

2.2.5 Primary packaging:

The labelling of each box of medicines packaged in bulk, and of each packaging unit of medical equipment will comply with standard W210 of the WHO rules of good practice, and will indicate in French or, failing that, in English:

* the name of the product under International Common Denomination,
* dosage and pharmaceutical form,
* the applicable pharmacopoeia standard
* the full identification of the manufacturer (name and full address),
* identification of the marketing authorisation holder (full name and address)
* the manufacturing batch number, manufacturing and expiry date,
* any special storage conditions,
* the number of units contained in each packaging unit.

Tablets and capsules packaged in films or blisters must bear either on each blister or on the blister pack the international common name, the dosage, the name and full address of the manufacturer, the batch number and the expiry date. The box containing these films or blisters must be labelled in the same way as the bulk box. The legal notices (batch number and expiry date) must be printed on the non-detachable part of the blister pack.

Injectable ampoules must have these details written in indelible, non-erasable ink or engraved on each of them.

These details must be printed in indelible ink, therefore non-erasable, or labeled on each other medicine and medical-surgical consumable presented in individual packaging.

Any medicine offered in individual packaging must contain a leaflet in French, however the leaflet in English is accepted duly accompanied by its translation into French.

2.2.6 Secondary and tertiary conditioning:

In addition to the mandatory information required by the pharmaceutical legislation of the product's country of origin, the external labelling of the grouping unit (carton) must state in French:

* the name of the product under International Common Denomination,
* dosage and pharmaceutical form,
* the full identification (name + address) of the manufacturer,
* the manufacturing batch number, manufacturing and expiry date,
* special storage conditions,
* the number of boxes contained in each packaging unit (carton).

2.2.7 Product Information Notice

Each medicine delivered under the Market will be accompanied by a short notice summarizing the main information available on the nature of the product, its conditions and precautions for use, and its storage conditions.

This notice will be attached to each primary packaging of the product.

The notice will be written in French. A notice in English is accepted duly accompanied by its translation into French.

The text of the notice will present successively and at least the following information, relating to the product:

* the detailed unit composition: nature and dosage of the active ingredient(s) and excipients;
* The reference pharmacopoeia
* presentation and form
* Product Property
* The fate of the product in the body (Pharmacokinetics));
* therapeutic indications;
* directions for use and dosage (adult and pediatric standards);
* contraindications;
* side effects and adverse reactions;
* drug interactions (incompatibilities);
* precautions for use and any warnings required (warnings on excipients with known effects must be specified)
* information for pregnant and breastfeeding women
* the conditions and precautions relating to storage and conservation.
* The complete list of excipients (according to the product formulation)
* The name and address of the manufacturer.
* The name and address of the marketing authorisation holder

ARTICLE 3: TECHNICAL CONFORMITY OF SUPPLIES

The following standards apply within the framework of the technical specifications of certain categories of articles.

3.1 Technical compliance of injectable massive solutions (isotonic saline, glucose serum, sodium bicarbonate solution, Ringer Lactate solution, mannitol)

The bottles must be of the EURO HEAD type.

3.2 Technical compliance of injectable ampoules

All injectable ampoules must be self-breakable.

3.3 Technical compliance of non-woven hydrophilic compresses

Sterile non-woven hydrophilic compresses must be made of purified cellulose, measuring 10 cm x 10 cm and 20 cm x 10 cm, folded format, weighing 40 g/m2, and 4 layers. Their absorption capacity must be 10 g/l. The breaking strength must be on average 35 N/5 cm and 14 N/5 cm across. They must not fray. They must have a bacterial contamination of less than 100 cfu/g.

They will be packaged in packs of 10 compresses in tamper-proof packaging, bearing the regulatory markings.

3.4 Compliance of Vitamin B complex tablets and injectables

Vitamin B complex tablets:

- Thiamine or vitamin B1 – 50 mg
- Cyanocobalamin or vitamin B12 -1 mg
- Pyridoxine or vitamin B6-100 mg

Vitamin B complex injectable:

- Thiamine or vitamin B1 – 100 mg
- Cyanocobalamin or vitamin B12 -1 mg
- Pyridoxine or vitamin B6-100 mg

3.5 Compliance of Multivitamins tablets, syrup and injectables

Multivitamin tablets:

- Vitamin A BP 800 IU
- Vitamin D3 BP 100 IU
- Vitamin B1 BP 0.5 mg
- Vitamin B2 BP 0.5 mg
- Niacinamide BP 7.5 mg

Multivitamin syrup/oral solution:

- Vitamin A (as palmitate): 550 IU
- Vitamin D3 (cholecalciferol): 35 IU
- Vitamin C (ascorbic acid): 10 mg
- Vitamin B1 (thiamine hydrochloride): 0.5 mg
- Vitamin B2 (riboflavin): 0.5 mg
- Niacinamide (vitamin B3): 5 mg
- Vitamin B6 (pyridoxine): 0.25 mg
- Iron (as ferric choline citrate): 10 mg

Multivitamin Drinkable Drops:

- Retinol (Vitamin A) - 2,500 IU
- Ergocalciferol (vitamin D2) - 500 IU
- Alpha-tocopherol (vitamin E) - 1 mg
- Thiamine (vitamin B1) - 1 mg
- Riboflavin (vitamin B2) - 0.75 mg
- Nicotinamide (vitamin PP) - 5 mg
- Dexpanthenol (vitamin B5) - 2 mg
- Pyridoxine (vitamin B6) - 1 mg
- Ascorbic acid (vitamin C) - 25 mg

Injectable polyvitamin:

- Vitamin A (Palmitate) - 10,000 IU
- Thiamine Hydrochloride - 50 mg
- Riboflavin Phos. Sod. - 10 mg
- Nicotinamide - 100 mg
- D-Panthenol - 25 mg
- Pyridoxine Hcl - 15 mg
- Vitamin E Acetate (Tocopheryl acetate) - 5 mg

3.5 Technical compliance of probes

- Nasogastric tubes must be made of transparent thermosensitive PVC with ORX line, open distal end, 4 side ports, centimeter marking from 5 to 75 cm, with a length of 100 to 125 cm.
- Gastric lavage tubes (Faucher tube) must be made of thermosensitive PVC, with an open distal end, 4 side holes, marked every 5 cm from 15 to 75 cm, and 150 cm long.
- Oxygen probes must be made of PVC, 40 cm long, terminal port, 8 side ports, with a universal green tip.
- Bronchial suction probes (De Lee type) must be made of PVC, open, straight and blunt end, a side orifice, 27 cm long for CH 8, 47 cm minimum length for CH 14, CH 16.

- Foley catheters should be made of silicone latex, straight cylindrical, 40 cm long, 2 or 3-way with a 30 ml balloon.

All probes must be

- single use;
- sterile and non-pyrogenic;
- packaged in an individual sterility protector in the form of a peelable sachet bearing the regulatory information and all instructions for use.

3.6 Technical conformity of synthetic wadding

The synthetic orthopedic wadding, sterilizable in an autoclave, is composed of 100% polyester water-repellent synthetic fibers. The required dimensions are 7.5 cm X 2.7 m.

The packaging will be individual, and a grouping can be made by 12 in tamper-proof packaging.

3.7 Technical compliance of adhesive bandages

The 10 cm x 5 m and 18 cm x 5 m perforated adhesive bandages must meet the following characteristics:

- roll of woven zinc oxide adhesive tape, flesh-colored or white, made of a hand-cut cellulose acetate backing
- coated on one side with a zinc oxide adhesive mass of normal skin tolerance, and of significant and prolonged adhesiveness, easy to handle for the user. Any unsatisfactory adhesiveness will not be accepted.
- perforated, hydrophobic, with serrated edge,
- with embossed polyethylene protector,
- and packaged in individual protective packaging with all instructions for use.

3.8 Technical compliance of epicranial needles (micro perfusers)

- Epicranial needles (micro perfusers) must meet the following standards: NFS 90 011, 90 013, 90 015, ISO 594-2, CE
- They will have the following constituent elements:
- □ a triple needlebevel;
- □ a protectorneedle;
- □ two standardized color fins (green for the 21G micro perfusers and blue for the 23G micro perfusers));

⇒ □ a transparent flexible PVC tube, 30cm longlength;

⇒ □ a terminal tipPE luer-lock, 6% taper, with obturator.

⇒ Each epicranial needle must be packaged in individual peelable blister packaging, including all the instructions for use, and grouped in boxes of 100.

⇒ Sterilization with ethylene oxide.

3.9 Technical compliance of catheter needles

Catheters must meet AFNOR NF S 90-040 standards.

Catheters must have:

⇒ a silicone-coated, triple-beveled needle with an orientation lug ensuring easier and less traumatic penetration;

⇒ a cannula at least 40 mm long for catheters less than 20 gauge

⇒ flexible fins ensuring a secure and comfortable fit

⇒ a transparent reflux chamber with hydrophobic membrane shutter and universal shutter.

⇒ An injection site

Catheters should be:

⇒ single use;

⇒ sterile and non-pyrogenic;

⇒ packaged in individual sterile packaging in the form of a peelable blister bearing the regulatory information and all instructions for use.

3.10 Technical compliance of perfusers

The infusers must meet the standards: AFNOR: NF S 90 202 or ISO 8536-4 or European Pharmacopoeia (CE). No leaks in the device are tolerated.

The infuser must include the following constituent elements:

- a perforator with built-in air intake with hydrophobic membrane, closable by valve, ensuring bacteriological filtration of the air;
- a transparent semi-rigid chamber with a dropper calibrated at 20 drops/ml, with a volume of 8 ml, with a particle filter (optional) with a porosity of 15 microns
- a flow regulator by roller clamp;
- a transparent PVC tube with an internal diameter of 3 mm and a length of at least 170 cm;
- a device for extemporaneous injections (Y-site or 3-way stopcock) located at a distance of at least 20 cm from the terminal tip. Injection sites located at a distance of less than 20 cm from the terminal tip are not accepted.
- Please note: New HIV precautions prohibit rubber injection sites interspersed within the PVC line.
- a male “luer lock” terminal tip;
- a 20 G vein needle accompanied.

3.11 Technical compliance of transfusers

Transfusers must meet AFNOR standards: NF S 90 202 or ISO 8536-4 or European Pharmacopoeia (EC). No leaks in the device are tolerated.

The transfuser must include the following constituent elements:

- a perforator with built-in air intake with hydrophobic membrane, closable by valve, ensuring bacteriological filtration of the air;
- a transparent semi-rigid chamber with a dropper calibrated at 20 drops/ml, with a volume of 8 ml, with a 10 cm2 filter with 200 micron mesh;
- a flow regulator by roller clamp;
- a transparent PVC tube with an internal diameter of 3 mm and a length of at least 170 cm
- An injection site or extemporaneous injection device (Y-site or 3-way stopcock) located at least 20 cm from the terminal tip. Injection sites located less than 20 cm from the terminal tip are not accepted.
- Please note: New HIV precautions prohibit rubber injection sites interspersed within the PVC line.
- a male “luer lock” terminal tip;
- a 21G vein needle accompanied.

3.12 Compliance of urine collection bags

It must meet ISO or NFS 90-631 standards.

The urine collection bag must have the following characteristics: made of transparent PVC with a white background, graduated in 100 ml, with a nominal volume of 2 liters, with a non-return valve and a push-pull drain tap. It is equipped with 2 reinforced suspension holes, a translucent tube 90 cm long, with an internal diameter of 5 mm, a notched connector with a cap, conical, standardized, adaptable to all bladder catheters and penile sheaths.

3.13 Technical compliance of X-ray films

X-ray films must be manufactured according to ISO 9002 or EN 46002 standards. They must be provided with interleaves or tropicalized (with supporting certificate).

3.14 Surgical glove compliance

Sterile surgical gloves must meet AFNOR standards: NF S 90 000, EN 455, or ISO.

Sterile single-use surgical gloves must meet the following requirements: made of natural latex, internally powdered with FDA-approved corn starch, anatomically shaped with right and left hand indications in double packaging, with a cuff with a wrist reinforced with a rolled edge, hypoallergenic.

- Size 7 surgical gloves should have the following dimensions: minimum length of 270 mm, palm width of 89 mm +/- 5mm.
- Size 7 ½ surgical gloves must have the following dimensions: length of 270 mm minimum, width at the palm of 95 mm +/- 5 mm.

Flexibility, elongation at break, tensile strength, fineness, ease of donning will be particularly observed. The double packaging must be easily peelable (with sagittal opening), to avoid asepsis errors as much as possible. Packaging to be cut with scissors is not accepted.
The single-use sterile surgical gloves will be packaged in pairs, in double-wrapped sachets with sagittal opening, and grouped in a box of 50 pairs.

3.15 Technical compliance of non-sterile examination gloves

Non-sterile examination gloves must meet AFNOR NFS 90 001 or ISO standards

⇒ **Compliance of non-sterile latex examination gloves, size medium (7/8)**

Non-sterile latex gloves must havethe following characteristics: made of natural latex, with an internal powder coating of resorbable organic corn starch. They must be ofambidextrous shape, and have a reinforced wrist with a rolled edge, and is hypoallergenic.

The required dimensions are: medium size (7/8), minimum length of 230 mm, palm width of 95 mm +/- 10 mm, minimum thickness of 0.08 mm.

⇒ **Compliance of non-sterile latex examination gloves size small (6/7)**

Size 6/7 non-sterile latex examination gloves should havethe following characteristics: made of natural latex, with an internal coating of resorbable organic corn starch. They must be ambidextrous in shape, and have a wrist reinforcement with a rolled edge, and hypoallergenic.

The required dimensions are as follows: size small (6/7), with a minimum length of 230 mm, a width at the palm of 80 mm +/- 10 mm, a thickness of 0.08 mm minimum.

The qualities of flexibility, resistance, and finesse will be particularly observed.

3.16 Technical conformity of scalpel blades

Scalpel blades must meet BS 2982 or ISO 7740 standards.

They must be made of stainless steel, sterilized by gamma rays, packaged in individual peelable packaging, easy to open (sagittal opening) grouped in boxes of 100 blades. Carbon blades are not accepted.

3.17 Technical compliance of wires and ligatures

Wires and ligatures must meet ISO 9000 or 9001, or EN 46001 standards.

Uncrimped wires must be packaged on a reel allowing easy unwinding of the wires.

3.18 Technical compliance of vitamin C 500mg tablets

In addition to the paragraph reserved for the Reference Pharmacopoeia of pharmaceutical products and their packaging, the information described below is specifically applicable to the following product:

Vitamin C or ascorbic acid dosed at 500 mg in tablets must be of the “chewable” or “suckable” type. This mention must be clearly visible on the blisters and on the boxes.

3.19 Technical compliance of insulins

Insulins must be in injectable suspension, of biogenetic human origin, pure or mixed according to their indications, and presented:

- in 10ml bottle containing 100IU per ml of suspension.

- or in 3 ml cartridges containing 100 IU per ml of suspension, packaged in boxes of 5 or 10 cartridges.

3.20 Requirements on the origin of the country of manufacture of Paracetamol 10mg/ml solution for infusion

Due to their narrow therapeutic margins, Paracetamol 10mg/ml infusion solutions must come from manufacturing sites in highly regulated ICH (International Conference of Harmonization) countries

(Europe, Japan, North America), or countries whose regulatory authorities are members of the PIC/S (Pharmaceutical Inspection Co-operation Scheme) (www.picsheme.org/).

3.21 Ban on advertising information on packaging boxes

The packaging boxes (secondary packaging) of medicines must not under any circumstances contain any advertising material (image or text).

3.22 International recommendations on the phased use of calcium gluconate solutions packaged in plastic containers

In order to limit patient exposure to aluminum, the use of calcium gluconate solutions packaged in plastic containers is recommended.

3.23 Reagent compliance

Manufacturers must follow the standards:
ISO 13485 for laboratory reagents and consumables
ISO 9000 series for products that do not fall into the category of ISO 13485 standards.

3.24 Compliance of arteriovenous lines with hemodialysis needles

- Universal line for Dialog, Gambro, Althin, Fresenius.
- Method ofsterilization: Radiation (validated for beta and gamma).
- Patient clamp colour coded, 2l drainage bag, Spike.

3.25 Compliance of concerted acid solutions for hemodialysis.

Packaging: 5L or 10L can
Composition :

1000ml of purified watercontains :

- Sodium Chloride 210.7 grams or 138mmmol/l ±5%
- Calcium Chloride 7.72grams or 1.50 mmmol/l ±5%
- Potassium Chloride 5.22grams or2.00 mmol/l ±5%
- Magnesium chloride 7.12 grams or 1.00 mmmol/l ±5%
- Acetic acid 6.31 grams or 3.0 mmmol/l ±5%

The legal notices on the container must be clear and complete.

3.26 Compliance of dialyzers or artificial kidneys

- High performance, low flux dialyzer (F6= 1.3 m2; F7= 1.6 m2; F8= 1.8 m2),
- α Polysulfone, sterilization by gamma radiation without oxygen.
- Ultrafiltration coefficient ml/h/mmHg QB = 300 ml/min 11-17;
- Clearance (dialysate flow = 500 ml/min, ultrafiltration flow (QF) = 0 ml/min) Urea: 192-310, creatinine: 180-290, phosphate: 150-220, vitamin B12: 90-130
- The packaging must contain all useful information: surface, marking, nature of sterilization, batch, sterilization date and expiry date.

3.27 Compliance of dual-flow catheters for hemodialysis

- Double lumen catheter 15-20 cm, incl.
- Valve cannula 18 G (1.3 mm),
- Marked guidewire with flexible J-tip in dispenser, 12 Fr dilator, scalpel, injection cap, connecting cable for intra-atrial ECG probe, syringe: 5 ml,
- Priming volume: 12-14 ml
- Flow rate: 200 - 240 ml/min distal; 240-270 ml/min proximal
- DEHP free

3.28 Compliance of bicarbonate cartridges for hemodialysis

Compatible with original dialysis machines, bicarbonate cartridge powder or granule in sufficient quantity for one dialysis session, 650g

The technical specifications of medical consumables and dental products are visible in the appendix

B.2. TECHNICAL CLAUSES RELATING TO THE SUPPLY

Features of the supply

1.1. TRANSPORT PACKAGING

The Supplier shall make all arrangements for packaging and wrapping to ensure that its Supplies are properly protected from damage during transport and storage. The Supplier shall be fully responsible for the quality of the packaging of the Products.

The packaging must offer the best guarantees to effectively protect the supplies during their transport to the “SALAMA” stores.

This protection concerns: general transport conditions, the specific climatic conditions of Madagascar, the specific packaging conditions required for medicines and consumables, the risks of deterioration of packaging and theft during transport.

Packaging is carried out under the responsibility of the supplier. Any packaging deemed defective upon receipt in the “SALAMA” stores will incur the supplier’s liability; in this case, the costs of returning the package or replacing the boxes will be at their expense or will be deducted from their invoice.

All crates or cartons must clearly indicate the following information:

On each package, a label of size (21 cm x 15 cm), readable from a distance of at least two meters, will indicate:

- the designation of the supply as appearing on the Price and Unit Quantity Schedule.
- the date of manufacture and expiry of the manufacturing batch
- the lot identification number
- the quantity contained in a box
- the weight of the package

A second label will specify the receiving address in Madagascar:

"SALAMA" - Central Purchasing of Essential Medicines and Medical Equipment of Madagascar

Lot III A 112 - Anjanamasina Anosiala - PK 18 RN 4

Ambohidratrimo District

105 ANTANANARIVO

MADAGASCAR

Tel: 032 02 290 22-034 97 469 24-034 13 469 25- 034 13 469 26

Email: salama@salama.mg

No crate or carton may contain products from different batches. These cartons or crates will be grouped on the same pallets.

Cold chain products must have a label indicating the storage temperature and the precautions to be taken:
Ex: +2 to +8°c, keep cool, heat-sensitive products, etc.
Any shipment, whether at room temperature or under cold chain, must be subject to temperature monitoring using a thermometer which records the temperature data of the data loger type shipment.

1.2 PACKAGING

The supplies delivered under the Contract will be presented in the manufacturer's original packaging and will comply with the packaging proposed during submission and award.

1.3 EXPIRATION DATE

The supplies must clearly show the date of manufacture and the expiry date (use-by date).

THE REMAINING SHELF LIFE OF THE PRODUCTS MUST BE GREATER THAN ¾ OF THEIR TOTAL SHELF LIFE FROM THE DATE OF RECEIPT IN THE SALAMA STORE.

If there are any requests for exemption from non-compliance with the remaining shelf life on the part of the supplier, he is required to request SALAMA's opinion in writing (email or letter) within three (3) days after receipt of the Purchase Order. Otherwise, SALAMA considers the acceptance and strict compliance with the agreed expiry date.

SALAMA has the right to accept or refuse the proposal depending on the state of their stock. In case of refusal, the supplier undertakes to respect the terms of the contract and to deliver a fresh batch meeting the agreed ¾ remaining shelf life.

The Supplier must indicate in its submission whether the Supply has a short life, and must explain the reason and specify the period of validity of the Supply from its date of manufacture.

1.4 CONFORMITY OF DELIVERIES

During the execution of the Contract, conformity checks or quality checks may be carried out by "SALAMA". In the event that the products thus checked by one or more laboratories do not comply with the samples submitted, or with the required standards, "SALAMA" reserves the right to terminate the Contract of the supplier concerned without compensation. In this case, the supplier may request a counter-expertise, at its own expense, from a laboratory approved by the WHO. "SALAMA" will keep the offending batches available to the supplier. The latter will have a period of three months to repossess them, the related transport costs being its responsibility. After this period, "SALAMA" reserves the right to destroy, without paying for them, the supplies deemed non-compliant. The destruction costs will be borne by the supplier and deducted from the final invoice. The pricing conditions relating to destruction operations will be set by SALAMA (collection, transport and processing). The number of non-conformities of technical specifications upon delivery will be reported in the supplier's performance evaluation.

1.5 LABELING MODE

The labelling must be written partially or entirely in French, and must indicate:

- the name of the product under International Common Denomination,
- the dosage or number of international units, determined in relation to WHO standards.
- the applicable standard
- the name of the technique used
- the complete identification of the manufacturer and the Control Institute
- the manufacturing batch number, manufacturing and expiry date,
- any special storage conditions,
- the number of units contained in each packaging unit.

1.6 STANDARDS AND QUALITY

All supplies must:

(a) meet the requirements of the laws and regulations governing the manufacture of pharmaceutical products in the country of origin;

b) comply with all the requirements indicated in the Special Technical Clauses;

(c) be certified by a competent authority of the country of the manufacturer or Supplier in accordance with resolution 28-65B of the World Health Organization's "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce".

(d) meet the requirements of the laws and regulations governing the manufacture and marketing of pharmaceutical products, as defined by the Madagascar Medicines Agency (AGMED).

1.7 Products under cold chain - Low temperature storage

With regard to supplies requiring low temperature storage (refrigerator or freezer), the Supplier will take, from the point of embarkation to the place of actual delivery, according to the conditions described in articles 1.1 of the Special Technical Clauses, all transport arrangements in order to transport these supplies in the perfect conditions required to ensure the continuity of the cold chain.

All products, including those under the cold chain, must be accompanied inside each package and during transport from the manufacturing site to SALAMA's stores, by an automatic temperature recording device, so that SALAMA can access the temperature data upon receipt of the goods.

The supplier is required to bear the costs of storing the products in a cold room under customs control.

1.8 Delivery conditions :

The following products will be delivered by air if their successful bidders are foreign suppliers

DESIGNATION
Phytomenadione (vit K1) 10 mg/ml amp 1ml
Regular insulin 100 IU/ML inj FL/10 ml
Intermediate insulin 100 IU / ml inj FL 10ml
Pancuronium Bromide 2 mg / ml inj – amp -
Injectable Anti-Tetanus Serum
Phenobarbital 40 mg/ml amp of 1 ml
Fentanyl 50µg/ml amp of 2ml
Fentanyl 50µg/ml amp of 10 ml
Ergometrine maleate 0.5 mg/ml inj 1ml – amp
Suture threads
Epinephrine Adrenaline INJ - amp

1.9 Products placed under international control

For the following items, the Supplier must be authorized by the competent Authorities of its country to export these products. “SALAMA” will obtain the import authorization from the Directorate of Pharmacy, Laboratory and Traditional Medicine (DPLMT) – and will send it to the Supplier.

Information on the basic weight of each product will be provided by the supplier.

Costs related to sending the documents will be charged to the supplier.

DESIGNATION	STATUTES
Diazepam 5 mg cp (blister)	(b)
Diazepam 5 mg/ 2ml – Inj -	(b)
Ergotamine-caffeine 1mg-100mg – tab -	(c)
Ergometrine maleate 0.5 mg – tab -	(c)
Ergometrine maleate 0.5 mg/ml amp 1ml	(c)
Fentanyl 100 µg/2ml amp inj 2ml	(has)
Fentanyl 500 µg/2ml amp inj 2ml	(has)
Phenobarbital 50 mg tablet (blister)	(b)
Phenobarbital 40 mg/ml inj	(b)
Morphine Hcl 10 mg/ml inj	(has)
Morphine 10 mg LP-cp	(has)
Morphine 30 mg LP-cp	(has)
Potassium permanganate 0.5 g – tab -	(c)
Nalbuphine 10mg/ml amp inj	(has)
Oxycodone 5mg cp	(has)
Pethidine 100mg/2ml amp inj	(has)
Hydromorphone LP 4mg gelu	(has)

Delivery of these products must be made in accordance with:

(a)- the Single Convention on Narcotic Drugs of 1962

(b)- the 1971 Convention on Psychotropic Substances

(c)- the Convention against Illicit Traffic in Narcotic Drugs

2. PACKAGING

In addition to the information described in article 1.2 of the Special Technical Clauses, each package delivered will be numbered and must imperatively include, under penalty of refusal of the goods, the following information:

- supplier name
- order number,
- corresponding delivery note number,
- number of units of each item

3 – PAYMENT AND DELIVERY DOCUMENTS

3.1 Shipping documents

Regarding the shipping documents, it is necessary for the supplier to send a prior copy of the documents by e-mail (Bill of Lading and/or Air Waybill, Invoice, Packing List, COA, COO) before sending the goods, in order to allow their verification and preparation of customs clearance procedures.

3.2 Payment documents

- Detailed commercial invoice in FOB PER ITEM, FREIGHT-INSURANCE, mentioning the manufacturers, countries of origin, expiration dates, and batch numbers of each product
- Copy of Bill of Lading or Air Waybill (AWB)
- Copy of expert report
- Copy of the proof of residence
- Copy Packing List
- Physical control and packaging control sheet
- The information that should be included on this list is as follows:
    - the order number of “SALAMA”
    - the unit quantities of each item shipped,
    - the number of packages for each product shipped,
    - the total weight and total volume of the delivery,
    - for products requiring cool storage, the corresponding volume.
- Cargo Tracking Note (CTS) Acceptable: SGS inspection is no longer required but you should register the shipment on the sitewww.bscmg.sgs.com
- SALAMA's ID number is 5497
- Contact Technical Center:MG.BSC@sgs.com
- Contact the supplier's freight forwarder in charge of customs clearance at the port or airport of disembarkation in Madagascar
- Any storage and/or demurrage costs incurred due to delays in customs clearance at the port or airport of disembarkation in Madagascar by the supplier will be borne by the supplier.

For local suppliers:

- Commercial invoices
- Delivery note
- Physical control and packaging control sheet

3.2 Customs clearance authorization for Medicines:

The supplier must ensure that the medicines are registered with the Madagascar Medicines Agency and send SALAMA the valid registration certificates before shipping the goods.

No shipment of medications should be carried out without a marketing authorization certificate.

Failure to comply with these rules may result in refusal of customs clearance of goods by the competent authorities. The SALAMA Purchasing Center cannot be held responsible for any damages resulting from this.

The request for authorization for customs clearance of Medicines under the MIDAC module will be made by SALAMA upon receipt of the final commercial invoice from the supplier, detailing FOB PRICE PER ITEM, FREIGHT COST, INSURANCE, and mentioning the NAMES OF THE MANUFACTURERS, the BATCH NUMBERS of the medicines delivered.

The approved Customs Clearance Authorization will be forwarded to the Supplier's Freight Forwarder by Salama

Any storage and/or demurrage costs incurred due to the delay in approving the customs clearance authorization will be borne by the supplier.

3.3 Delivery documents:

The supplier must attach to each delivery:

- Certificate of analysis for each batch of items delivered (mandatory before any receipt)
- Certificate of origin of products
- Certificate of sterility for sterile consumables
- Delivery note: two originals

Each delivery will be accompanied by a delivery slip which will indicate, for each package:

- the order number of “SALAMA”,
- the number of units contained in the delivery for each item,
- the item number,
- the designation of each item,
- the price per item,
- the total quantity delivered
- the total price of delivery.

4 – CONTROL AND ADMISSION

4.1 RECEPTION

Before shipping, any goods subject to registration must have the approval of the artwork and the notice by the Quality Assurance Department. Photos and videos of the products must be provided before shipping. The reception by "SALAMA" consists of checking the conformity in quantity and quality (according to the sample provided and validated) of the items delivered with the requirements of the specifications of this call for tender. "SALAMA" will have a period of 30 (thirty) days from the day after the date of receipt in its stores, to quantitatively accept the supplies and a period of 60 (sixty days) from the day after the date of receipt in its stores, to qualitatively accept the supplies. The availability of the COA is mandatory upon physical receipt (electronic sending / physical sending).

Salama Office and Store Opening Hours: 7:30 a.m. to 3:45 p.m. (local time)

4.2 DAMAGED AND MISSING

In the event of damage or possible shortage noted by an approved expert, affecting supplies, “SALAMA” will deduct the amount of the damaged or missing goods from the commercial invoice.

In the event that the amount of damaged or missing goods reaches more than 25% of the amount of the delivery, the Supplier will be required to replace the defective or missing supplies within one month, by air delivery (if foreign supplier). All costs relating to this new delivery (freight, insurance, customs duties, taxes, approach costs) will be borne by the supplier.

4.3 REPLACEMENT OF NON-CONFORMING SUPPLIES

In the event of non-conformity of the supplies delivered with respect to the Contract, noted by an authorized expert, the Supplier will be required to replace the defective supplies within one month, by air delivery (if foreign supplier). All costs relating to this new delivery (freight, insurance, customs duties, taxes, approach costs) will be borne by the supplier.

4.4 POSITIVE QUALITY CONTROL

“SALAMA” may at any time carry out a quality control of the products with an independent laboratory of its choice. The costs relating to the quality control will be borne by “SALAMA”.

If, following the inspection, the products are found to be non-compliant, "SALAMA" will notify the supplier in writing. The supplier may request a counter-expertise at its own expense from a laboratory approved by the WHO. "SALAMA" reserves the right to inform the supervisory authorities, as well as the services responsible for the WHO Certification Scheme in the event of serious problems.

The Supplier shall be required to replace non-compliant Supplies within one month.

If the non-conforming Supplies are not recovered within a deadline of 60 (sixty days) by the supplier and at its expense, they will be destroyed by “SALAMA”. The costs of destruction will be borne by the supplier and deduces of the final invoice. The pricing conditions relating to the destruction operations will be set by SALAMA (collection, transport and processing)

4.5 TECHNICAL CONDITIONS OF ACCEPTABILITY

In conclusion, to avoid any inconvenience due to the refusal to receive the delivered products and their payment, each supplier is required to respect:

- The required expiration date
- Completeness and conformity of documents upon delivery (certificate of analysis for each batch)
- Delivery time

4.6 NON-COMPLIANCE FOUND FOLLOWING A QUALITY COMPLAINT

Following a quality complaint, SALAMA may at any time recall a batch of non-compliant products, informing the supplier at the same time.

The supplier is required to provide an explanation and an action plan following a proven quality complaint (confirmed by laboratory analysis); each complaint must be communicated by SALAMA to the supplier and must be closed within a reasonable time.

SALAMA reserves the right not to request a replacement of the goods, but to deduct the full amount of the batch concerned from the supplier's invoice payments, and cannot be required to reimburse the amount of non-compliant products not returned by customers.

If the non-conforming goods are not collected within 60 days (sixty days) by the supplier at its own expense, they will be destroyed by SALAMA. The costs of destruction will be borne by the supplier. The costs of destruction will be borne by the supplier and will be deducted from current or future invoices.

In the event of a proven complaint, an investigation will be carried out beforehand by SALAMA and shared with the supplier with all the information justifying the non-conformity (quantity concerned, photos, etc.), the supplier undertakes to respond within a maximum of 5 working days.

This response time may be reduced in the event of non-compliance depending on the level of criticality of the dispute. The existence and response time to complaints will be assessed during the performance evaluation of the supplier.

In the event of an anomaly or recurring non-conformity, a financial package will be requested by SALAMA to compensate for the damage and the stock shortage that this could cause.

4.7 SUSPENSION OF AMM OR PROBLEMS INHERENT TO PHARMACOVIGILANCE

Following a refusal or suspension or cancellation of MA, notified by the National Regulatory Authority, or following any problem related to pharmacovigilance or any other decision notified by the competent authorities of the country, SALAMA will proceed to the immediate quarantine of the products concerned and the recall of the batches in circulation. The removal or destruction of the products will be at the supplier's expense. SALAMA reserves the right to deduct the full amount of the batch concerned from the supplier's invoice payments, and cannot be required to reimburse the amount of non-compliant products not returned by customers.

PART THREE: SUBMISSION FORMS

Appendix No. 1: LETTER OF COMMITMENT

CENTRAL PURCHASING CENTRE FOR ESSENTIAL MEDICINES AND MEDICAL EQUIPMENT

"SALAMA"

ACT OF COMMITMENT

ARTICLE 1-Subject of the International Call for Tender and the Commitment Act

This act of commitment corresponds to the basic offer for the referenced International Call for Tenders **AOI 1/25,**launched by the Central Purchasing Office for Essential Medicines and Medical Equipment of Madagascar "SALAMA", for the supply of Essential medicines, medical consumables and dental products, hemodialysis consumables and anti-cancer products and new products.

ARTICLE 2 -Commitment

I, the undersigned (Name, first name).....

acting as (quality).....

in the name and on behalf of (power of attorney to be attached) .....

whose head office is at (business address) .....

.....

and electing my domicile at (personal address) .....

.....

After having taken note of the Mission of SALAMA as a non-profit Association, "to supply public health facilities and non-profit organizations with generic Essential Medicines and medical consumables appearing on the latest National List published by the Ministry of Public Health"

After having read the Administrative and Technical Clauses of this International Call for Tender AOI 1/25,

After having personally informed myself, and having assessed from my point of view, and under my entire responsibility, the nature and difficulty of the Supplies to be carried out,

I submit and undertake to deliver the Supplies listed on the summary submission form, in accordance with the conditions set out in the International Call for Tender documents, all of the parts of which I have signed and accepted without reservation, for the total price DDP SALAMA ANTANANARIVO MADAGASCAR INCLUDING non-revisable VAT of:

.....

.....

Resulting from the unit prices, which I established myself, applied to the quantities indicated in the schedule of quantities and unit prices of the International Call for Tender documents.

ARTICLE 3– Unit price

The unit prices of the quantity schedule and unit prices of this Contract are understood to be DDP SALAMA ANTANANARIVO MADAGASCAR including the various taxes if any.

ARTICLE 4 –Registration of pharmaceutical products with the Madagascar Medicines Agency (AMM)

I undertake to ensure that all pharmaceutical products allocated are registered with the Madagascar Medicines Agency, and to send SALAMA all documents with a view to obtaining marketing authorization within the allotted time.

ARTICLE 5 -Time limit

I further undertake to deliver within the time limits as indicated in the financial offer the supplies of the items which will be awarded to me under this Contract within the time limits indicated by me in the schedule of quantities and unit prices. I have taken due note of the penalties for delay provided for in the special clauses.

ARTICLE 6 – Regulations

I accept the following payment methods**:**

- Payment method: By check for local suppliers and by bank transfer for foreigners
- Payment terms:
  - ✓ 100% within 60 days from the date of receipt of the goods against a performance bond equal to 10% of the contract amount (if applicable).

Or, for contracts with a total amount greater than USD 26,000 or EUR 20,000 or MGA 90,000,000:

- ✓ 30% in advance against an equivalent bank guarantee and a performance bond equal to 10% of the contract amount,
- ✓ 70% within 60 days from the date of receipt of goods

Payments of the amounts due under this Contract will be made on

account no. .....

open with .....

has.....

in the name of.....

Original RIB to be inserted

ARTICLE 7 – Declaration of activity

I declare that I have been carrying out, in accordance with the regulations and professional practices in force in the country where my company's headquarters are established, the activity of manufacturing and trading in medicines and/or medical consumables and/or medical equipment and/or laboratory reagents since .....…… Years (in words).

ARTICLE 8 – Regular declaration of situation

I affirm, under penalty of automatic termination due to the exclusive fault of .....

.....

for which I am intervening, that it does not fall under the scope of legal prohibitions issued either in Madagascar or in the State where its headquarters are established.

ARTICLE 9 – Validity period of the offer

This commitment binds me for the period of validity of the offers indicated in the Special Data of the International Call for Tender DPAOI 8 of the International Call for Tender file, i.e. until 12/31/25 and for all awards before this date.

ARTICLE 10- Conformity of products

I undertake to supply the product under the contract in strict compliance with the specifications validated by SALAMA.

ARTICLE 11- Performance bond

I undertake to provide a performance bond for any contract whose total amount exceeds 1500 USD or 1200 EUR for foreign suppliers.

Or the equivalent in local currency MGA for local suppliers (Exchange rate on the date of order allocation)

ARTICLE 12- Environmental and social commitment

I undertake to respect and ensure that all of my subcontractors respect the environmental and social standards recognized by the international community in terms of environmental protection and labor law, including the fundamental conventions of the International Labor Organization (ILO) and international conventions on the environment, in accordance with the laws and regulations applicable to the [country where the Project is carried out].

I also undertake to implement environmental and social risk mitigation measures as defined in the environmental and social management plan or, where applicable, in the environmental and social impact statement provided by SALAMA.

Do

HAS .....

THE .....

Duly authorized to sign an offer for and on behalf of……

(signature and stamp)

(Names and title)

Appendix No. 2: MODEL OF ADVANCE GUARANTEE

(BANK GUARANTEE)

_____*[insert name of Bank and address of branch or agency issuing the guarantee]*

Beneficiary: _____*[insert name and address of Buyer]*

Date: _____

ADVANCE GUARANTEE No: _____

NWe have been informed that [insert name of Supplier] (hereinafter referred to as "the Supplier") has entered into Contract No [insert Contract reference number] dated [insert date] with you for the supply of [insert description of Products] (hereinafter referred to as "the Contract").

Further, we understand that, in accordance with the provisions of the Agreement, an advance payment in the amount of [insert amount in figures] (_____) [insert amount in words] must be made against an advance guarantee.

At the Supplier's request, we [insert name of Bank] irrevocably undertake to pay you any amount or amounts not exceeding a total of [insert amount in figures] ([insert amount in words]) upon receipt by us of your first written demand accompanied by a written statement establishing that the Supplier is in breach of its obligations under the Contract as the Supplier has used the advance for purposes other than the supply of the Products.

One of the conditions of the claims for payment under the Guarantee is that the advance mentioned above has been deposited into Supplier's account number _____ [insert account number] with _____ [insert name and address of Bank].

This Guarantee will expire at later upon receipt by us of a copy(ies) of _____ or on _____ 2_____[1], whichever is the earlier. Accordingly, any claim for payment under this Guarantee must be received by us at our offices before or on that date.

This guarantee is governed by the provisions of the Uniform Rules on Guarantees, ICC Publication 458.

_____

[signature(s)]

Appendix No. 3: MODEL OF DEPOSIT OR PERFORMANCE GUARANTEE

_____*[insert name of bank and address of agency or branch issuing the guarantee]*

Beneficiary: _____*[insert name and address of Buyer]*

Date: _____

Performance Guarantee Number: _____

We have been informed that [insert name of Supplier] (hereinafter referred to as "the Supplier") has entered into Contract No [insert Contract reference number] dated _____ with you for the supply of [insert description of Products] (hereinafter referred to as "the Contract").

Furthermore, in accordance with the terms of the Agreement, we understand that a Performance guarantee is required.

At the Supplier's request, we [insert name of Bank] irrevocably undertake to pay you any sum not exceeding a total amount of [insert amount in figures] ([insert amount in words]), upon receipt of your first written demand accompanied by a written statement establishing that the Supplier has breached its obligations under the Contract, without you having to prove or demonstrate the validity of your demand or the specified sum.

The Guarantee will expire no later than _____ 2_____. Accordingly, any claim for payment under this Guarantee must be received by us at our offices on or before that date.

This Guarantee is governed by the provisions of the Uniform Rules for Guarantees, ICC Publication No. 458 excluding subparagraph (ii) of paragraph 20(a) which is hereby excluded.

_____
[signature(s)]

Appendix No. 4: MODEL MARKET CONTRACT

MARKET CONTRACT NO.

FOR THE SUPPLY OF ……..

WALK : …

Holder: SUPPLIER NAME

Head office address:

ADR1
ADR2
COUNTRY

Item Designations

ITEM N°	DESIGNATION	CONDT	UNIT QUANTITY	DDP SALAMA UNIT PRICE in (MONETARY UNIT)	AMOUNT DDP SALAMA in (MONETARY UNIT)	MANUFACTURER	COUNTRY OF ORIGIN	FULL ADDRESS OF THE MANUFACTURER'S WEBSITE	EXPIRY DATE	PRODUCTION TIME	DELIVERY TIME	TOTAL DELIVERY TIME

Delivery time: THAT MENTIONED IN THE ALLOCATION SLIP

Payment method: - CHECK FOR LOCAL SUPPLIERS
- WIRE TRANSFER FOR FOREIGN SUPPLIERS

Payment terms:

- ✓ **100% within 60 days from the date of receipt of the goods against a performance bond equal to 10% of the contract amount**

Or

- ✓ **30% in advance against an equivalent bank guarantee and a performance bond equal to 10% of the contract amount,**
- ✓ **70% within 60 days from the date of receipt of goods**

Amount DDP SALAMA ANTANANARIVO in figures:

Amount DDP SALAMA ANTANANARIVO in words:

Done at ……, on ……. Done in Antananarivo, on …….

For the supplier
(Read and approved, in handwritten letter)

The General Manager of SALAMA
Mieja Vola RAKOTONARIVO

MARKET N°

Between :

The Management of Salama, Central Purchasing Office for Essential Medicines and Medical Equipment of Madagascar, hereinafter referred to as “the Buyer”, and represented by Mrs. Mieja Vola RAKOTONARIVO, General Manager.

on the one hand,

and, (Name, first name, capacity):

acting in the name and on behalf of the company:

whose head office is located:

registered in the commercial register of:

under No.:

hereinafter referred to as “the Supplier”,

IT IS HEREBY DECIDED AND AGREED AS FOLLOWS:

Article 1: Purpose of the Contract

The offers, summarized in the final table of prices and unit quantities, confirmed by the Supplier, have been accepted by SALAMA.

No subsequent modification of this offer confirmed by the Supplier and accepted by Salama will be permitted, whatever its nature (change of price, packaging, dosage, deadlines, origin, manufacturer, etc.).

Article 2: Amount of the Contract

The amount of the market is set at the sum of (in figures):

in letters:

fixed and non-revisable hereinafter referred to as “the market price”.

Article 3: Definitions

In this market, the terms and expressions will have the same meaning as the meaning given to them in the restricted call for tender/SALAMA consultation document to which it refers.

Article 4: Documents constituting the contract

- Supplier offers:
  - Act of commitment
  - Quantity slip and unit price
  - Technical specifications schedule
  - The terms of the International Call for Tender Document AOI1/25

Done at ...……, on ..... Done in Antananarivo, on .....……..

For the supplier
(Read and approved, in handwritten letter)

The General Manager of SALAMA
Mieja Vola RAKOTONARIVO

GENERAL ADMINISTRATIVE CLAUSES (CCAG)

This General Administrative Clauses Book (CCAG) is the document applicable to the markets for the supply of pharmaceutical products from the Central Purchasing Office for Essential Medicines and Medical Equipment of Madagascar "SALAMA". It specifies the general purchasing conditions.

1 – Definitions

In this Restricted Call for Tenders document, the following terms shall be interpreted as follows:

"Contract" means the agreement between the Contracting Authority and the Contractor, as described and governed in all the documents constituting this file.

“Contractual Documents” means the documents referred to in the contract form, including any amendments to said documents.

"Contract Price" means the contract price payable to the Supplier for the complete and satisfactory performance of the services provided under the contract.

“Products” or “Supplies” means all items which the Supplier is required to deliver to the Buyer in performance of the Contract.

“Services” means, depending on the subject of the contract, supplies of medicines and medical consumables, and/or medical equipment and services.

The Buyer or “SALAMA” means the Contracting Authority for whose benefit the services provided for under the contract are carried out.It is also the contracting authority.

"Holder" means the bidder or supplier whose offer has been accepted and who concludes the contract with the contracting authority.

“Letter of award” means service order to commence services and is also considered “order confirmation” or “purchase order”.

"Notification" is the act of bringing information or a decision to the attention of the contracting party(ies) by any physical or electronic means enabling the date of its receipt to be determined with certainty. The date of receipt, which may be stated on a receipt, is considered to be the date of notification.

“Delivery” means the transfer of ownership of the Supplies from the Supplier to SALAMA, in accordance with the terms stipulated in the Contract.

“receipt” is the decision, taken after verifications, by which the Buyer acknowledges the conformity of the services with the stipulations of the contract. The decision of receipt is worth attestation of service provided and constitutes the starting point of the warranty periods;

"Admission" is the decision, taken after verifications, by which the contracting authority recognizes the conformity, without reservations, of the services with the stipulations of the contract. The admission decision is equivalent to a certificate of service provided.

“adjournment” is the decision taken by the contracting authority which considers that the services could be received subject to corrections to be made by the Supplier;

“rejection” is the decision taken by the Buyer who considers that the services cannot be received, even after adjournment

"Reservations" are all findings of non-compliance with the provisions of the contract, made during the checks prior to admission, which are brought to the attention of the holder and which prevent the awarding authority from issuing the admission decision. In the event of reservations, the admission decision is postponed.

2 – Contractual documents

Subject to the order of precedence set out in the Contract form, all documents constituting the Contract (and all parts of said documents) are correlative, complementary and mutually explanatory.

These general conditions will apply to the extent that they are not superseded by other contractual provisions contained in the Restricted Call for Tenders/Consultation documents.

3 − Fraud and corruption

3.1 The Buyer's rule is to ask Bidders and Suppliers to observe, when awarding and executing these contracts, the strictest rules of professional ethics. By virtue of this principle,

The Buyer:

a) defines, for the purposes of applying this provision, the terms and expressions below as follows:

Any person who offers, gives, solicits or accepts any advantage with a view to influencing the action of a public official during the award or execution of a contract is guilty of “corruption”.

(i) engages in “fraudulent tactics” whoever distorts or misrepresents facts in order to influence the award or execution of a contract;

(ii) "collusive practices" means any form of agreement between two or more bidders (whether or not SALAMA is aware of it) aimed at artificially maintaining the prices of bids at levels which do not correspond to those which would result from the play of competition;

(iii) “coercive practices” means any form of harm to or threats against persons or their property in order to influence their actions during the award or performance of a contract; and

b) SALAMA following its own investigations and conclusions, carried out in accordance with its procedures:

i. will reject a proposal for award if it determines that the proposed awardee is, directly or through an agent, guilty of corruption or has engaged in fraudulent, collusive or coercive practices in connection with the award of this contract;

ii. will declare a firm ineligible, either indefinitely or for a specified period, for procurement if, at any time, the firm has engaged in corruption or fraudulent manoeuvres, collusive or coercive practices, during the award procedure or the execution of the Contract. In this case, the firm will be prohibited from participating in SALAMA procurement for a period determined by SALAMA.

3.2 SALAMA reserves the right, when it has been established by a national or international body that a firm has engaged in corruption or fraud, to declare this firm ineligible, for a given period, for SALAMA markets.

3.3 SALAMA shall have the right to include in contracts a provision requiring bidders, suppliers, contractors, and consultants to permit SALAMA to inspect their accounts and records relating to the performance of the contract and to have them audited by auditors appointed by SALAMA.

3.4 Any communication between the Bidder and SALAMA relating to allegations of fraud or corruption must be in writing.

3.5 SALAMA declares that the negotiation, award and execution of the Contract has not given, does not give or will not give rise to acts of corruption within the meaning of the OECD Convention of December 17, 1997 on the fight against bribery of international public officials.

4 − INTERPRETATION

4.1 Incoterms

a) Unless otherwise specified in the CCAP, the meaning of the commercial terms and the rights and obligations assumed by the parties are those prescribed by Incoterms 2010.
b) EXW, FOB, CIF, CIP, DDP and other similar terms shall be governed by the rules prescribed in the latest edition of Incoterms published by the International Chamber of Commerce at the date of the invitation to tender.

4.2 Entirety of the agreements

The Contract represents the entirety of the contractual provisions agreed upon by SALAMA and the Supplier relating to its subject matter, and it supersedes all communications, negotiations and agreements (whether written or oral) entered into between the parties relating to its subject matter prior to the date of the Contract.

4.3 Amendments

Amendments and other modifications to the contract may only come into force if they are made in writing, dated, if they expressly refer to the contract and are signed by a duly authorized representative of each of the parties to the contract.

5 − MARKET LANGUAGE

The offer and all correspondence and documents relating to the submission, exchanged between the Bidder and the Buyer, will be written in French or English.

6 − NOTIFICATION

Any notice given to either party by the other party under the Contract must be in writing to the address specified in the CCAP. The expression “in writing” means sent in writing with acknowledgement of receipt.

A notice takes effect on the date on which it is delivered or on the date on which it becomes effective, whichever is the later.

7 − SIGNATURE OF THE CONTRACT

7.1 At the same time as notifying the successful Bidder of the acceptance of its offer, the Buyer will send it the model Contract appearing in the Restricted Tender Documents, by e-mail, including all the provisions agreed between the parties.

7.2 Within ten (10) days of the notification date, the successful Bidder shall sign and date the Contract and return the scanned version to the Purchaser by email; then send the document in two copies (one original and one copy), accompanied by the Performance Guarantee (See Clause 18 below) by express mail within thirty (30) days of the notification.

The physical version of the contract, after signature by SALAMA, will then be returned to the suppliers by express mail.

8 − APPLICABLE LAW

The Contract is governed by and construed in accordance with the law of the country of the Buyer "SALAMA".

9 − SETTLEMENT OF DISPUTES

9.1 "SALAMA" and the Supplier will make all necessary efforts to settle, amicably, by direct and informal negotiation, any disagreements or disputes arising between them under the Contract.

9.2 If thirty days after the start of negotiations for an amicable settlement, "SALAMA" and the Supplier have been unable to settle a dispute arising from the Contract, each party may request that the settlement of the dispute be subject to the procedures specified in the Special Clauses. These procedures may include, but are not limited to, conciliation in the form of mediation by a third party, referral for judgment to a national or international court and/or international arbitration. The method of recourse chosen will be specified in the Special Clauses.

10 − SUBJECT OF THE CONTRACT

The Market covers the Supply of essential medical consumables-medicines,

The quantity is shown in the quantity and unit price schedule of each supplier under this Restricted Call for Tenders.

11 − DELIVERY

Delivery of the Supplies and completion of the Related Services will be made in accordance with the delivery and completion schedule set out in the Delivery Schedule, which will set out the details of the shipment and specify the other documents to be presented by the Supplier.

Early deliveries will be accepted, subject to:

- SALAMA's acceptance of early delivery, acceptance materialized in writing (email or letter)
- That payment of the related invoices only occurs 60 days after the delivery date.

12 − RESPONSIBILITIES OF THE SUPPLIER

The Supplier shall provide all Supplies and related services included in the subject of the Contract and the delivery schedule while taking into account the delivery time and the incoterm mentioned in the award note.

13 − RESPONSIBILITIES OF SALAMA

The Supplier shall provide all Supplies and related services included in the subject of the Contract and the delivery schedule while taking into account the delivery time and the incoterm mentioned in the award note.

For the execution of the contracts, the supplier must strictly follow the steps mentioned in the "CONDITIONS OF EXECUTION OF THE CONTRACT", p.4

Any shipment, whether at room temperature or under cold chain, must be subject to temperature monitoring using a thermometer which records the temperature data of the data loger type shipment.

14 −QUALITY GUARANTEES

14.1 The Supplier warrants the quality of all Supplies delivered in performance of the Contract. The Supplier further warrants that the Supplies delivered in performance of the Contract will not have any defects due to their manufacture, the raw materials used or their use, or to any act or omission of the Supplier, occurring during the normal use of the Supplies delivered under the conditions prevailing in the country of final destination.

14.2 This warranty will remain valid until the expiration date of the products.

14.3 “SALAMA” will notify the Supplier in writing of any claim involving this guarantee.

14.4 Upon receipt of such notification, the Supplier will, within a maximum period of 30 (thirty) days, repair or replace the defective supplies or their parts, at no cost to “SALAMA”.

14.5 If the Supplier, after notification, fails to rectify the defect(s) within the required time period, “SALAMA” may begin to take the necessary measures, at the Supplier’s risk and expense and without prejudice to any recourse by the Supplier against “SALAMA” under the terms of the contract.

14.6 Products under cold chain must comply with the conditions mentioned in clause 21.3 of the CCAG. The supplier is responsible for maintaining the cold chain up to the agreed delivery point according to the incoterm, by deploying the equipment adapted for this purpose. In the event of non-compliance, SALAMA reserves the right to refuse receipt (according to the level of risk per product, e.g. insulin, etc.)

The prices that the Supplier will charge for the Supplies delivered and the services rendered in execution of the contract will not vary from the prices indicated in its offer.

15 – MARKET PRICE

The prices that the Supplier will charge for the Supplies delivered and the services rendered in execution of the contract will not vary from the prices indicated in its offer.

16 – DELAY BY THE SUPPLIER

16.1 The delivery of the supplies and the execution of the services will be carried out by the Supplier in accordance with the schedule specified by “SALAMA” in the special clauses.

16.2 Any delay by the Supplier in fulfilling its delivery obligations will expose it to one or all of the following penalties:

- Termination of the Contract for failure to perform and/or
- Imposition of penalties; and/or
- Seizure of his performance bond
- Reduction of the allocated quantity

16.3 If, at any time during the performance of the Contract, the Supplier has circumstances that prevent it from delivering the supplies in a timely manner, the Supplier shall promptly notify “SALAMA” in writing, informing it of the existence of the delay, its probable duration and its cause(s). As soon as possible after receipt of the Supplier's notification, “SALAMA” shall assess the situation, it shall have full discretion to extend the delivery or performance deadline, in which case the extension shall be ratified by the parties by amendment to the contract.

17 − PAYMENT TERMS

17.1 The price of the Contract will be settled in accordance with the provisions of the CCAP.

17.2 The Supplier shall submit the required documents to SALAMA, accompanied by invoices describing, in an appropriate manner, the supplies delivered and the related services rendered, and the exhibits presented, and after having satisfied all the obligations specified in the Contract.

17.3 Payments due to the Supplier will be made without delay by SALAMA, and at the latest within sixty (60) days following the presentation of the invoice and the documents required by the Supplier, and after its acceptance by SALAMA.

17.4 The currency(ies) in which payments will be made to the Supplier under the Contract will be the currency(ies) in which the tender price is stated.

18 − GUARANTEE OR SECURITY OF GOOD PERFORMANCE

18.1 Within thirty (30) days of receipt of the award of the Contract, the Supplier shall provide a guarantee for the proper performance of the Contract, for the amount specified in the CCAP.

18.2 The amount of the guarantee will be payable to SALAMA as compensation for any loss suffered due to the Supplier's failure to perform its contractual obligations.

18.3 The performance guarantee will be denominated in the currency of the Contract, and presented in the form stipulated in the CCAP or in another form acceptable to SALAMA.

18.4 The validity of the performance bond is ONE YEAR.

18.5 SALAMA will release and return to the Supplier the performance guarantee no later than thirty (30) days after the date of execution of the obligations incumbent on the Supplier under the Contract.

19 − CONFIDENTIAL INFORMATION

19.1 “SALAMA” and the Supplier shall respect the confidential nature of any document, data or other information provided directly or indirectly by the other party under the Contract, and shall not disclose them without the written consent of the other party, whether such information was provided before, during or after the execution or termination of the Contract.

19.2 “SALAMA” shall not use any documents, data and other information received from the Supplier for purposes other than those of the Contract. Similarly, the Supplier shall not use any documents, data and other information received from SALAMA for purposes other than the acquisitions or other works and services required for the execution of the Contract.

19.3 The above provisions do not in any way modify any confidentiality undertaking given by either party before the date of the Contract on all or part of the supply.

19.4 The provisions of clause 19 of the CCAG shall survive the completion or termination of the Contract, for whatever reason.

20 − SUBCONTRACTING

Within the framework of this market, no subcontracting will be authorized.

21 −PACKAGING AND DOCUMENTS

21.1 The Supplier shall package the Supplies in the manner required to ensure that they do not suffer damage or deterioration during transport to their final destination, in accordance with the provisions of the Contract. During transport, the packaging shall be sufficient to withstand rough handling and extreme temperatures, salt and precipitation, and open-air storage in all circumstances. The dimensions and weight of the crates shall take into account, whenever necessary, the fact that the final destination of the Supplies is remote and the possible absence, at all stages of transport, of heavy handling equipment.

21.2 The packaging, marking, labelling and documentation inside and outside the crates will strictly comply with the provisions specified in the Contract as well as with subsequent instructions, where applicable, in application of the CCAP, and with any other instructions given by SALAMA.

21.3 All products, including cold chain products, must be clearly identified by indicating the required temperature on the package/shipping document and have a temperature recording device (such as logtag, sensitech, haier or others).

21.4 Unless otherwise specified in the CCAP, the supplies delivered in execution of this Contract will be fully insured against any loss or damage arising from their manufacture or acquisition, their transport, their storage and their delivery in accordance with the Incoterms in force or in the manner specified in the CCAP.

22 − TRANSPORT

Unless otherwise specified in the CCAP, responsibility for the transport of the Supplies is assumed by the party specified in the Incoterms referred to in the Schedule of quantities and delivery schedules.

23 − PENALTIES AND SEIZURE OF THE PERFORMANCE GUARANTEE

Subject to the provisions of clause 10 of the General Clauses, if the Supplier fails to deliver any or all of the Supplies, or to render the services provided for within the time(s) specified in the Contract, "SALAMA", without prejudice to any other remedies it may have under the Contract, may deduct from the price thereof, as penalties, an amount equivalent to that indicated in the General Clauses, calculated pro rata to the value of the supplies suffering the delay for each day of delay before actual delivery, up to a maximum amount of 10% of the price of said Supplies. Once this maximum is reached, "SALAMA" may consider terminating the Contract, and awarding the Contract to another Supplier.

SALAMA reserves the right to seize the performance bond in the following cases:

- Withdrawal for any reason whatsoever (including price increase, insufficient quantity without mention of MOQ in the initial offer, non-compliant delivery, etc.)

- In the event that the performance bond has not yet been received by SALAMA, the latter reserves the right to deduct the amount relating to the bond from the current or future invoice(s).

24 − TERMINATION AND WITHDRAWAL

24.1 Termination for Non-Performance and Discontinuance

The “SALAMA” Purchasing Center may, without prejudice to other remedies available to it under the Contract, notify the Supplier of the termination of part or all of the Contract under the following conditions:

(a) if the Supplier fails to deliver any or all of the Goods within the time(s) specified in the Contract;

(b) if the Supplier fails to perform any other of its obligations under the Contract, in particular with regard to the quality of the Goods;

(c) In the event of the occurrence of force majeure events and whenever “SALAMA” considers that the delay risks compromising its activities.

If, after the award, the Holder withdraws and does not deliver one or more products awarded to it, the “SALAMA” Purchasing Center will terminate the contract by simple notice by email.

(d) If the Holder withdraws after signing the contract or during the period of validity of the offers for part or all of the contract, SALAMA will seize its performance bond and it will be suspended during the next Restricted Call for Tenders of “SALAMA” on the products which were the subject of the withdrawal during this Call for Tenders.

24.2 Termination due to insolvency

“SALAMA” may terminate the Contract at any time by written notice, without prejudice to its rights, if the Holder is declared bankrupt or becomes insolvent.

24.3 Discretionary termination

"SALAMA" may also, despite the fact that the holder is not in default, terminate the Contract in part or in full, at any time and at its discretion. If it exercises this right, the termination notice will specify that the termination occurs unilaterally at its discretion and the extent to which the performance of activities under the Contract ends as well as the date on which the termination becomes effective.

Goods manufactured and ready for shipment to “SALAMA” within 30 days from the date of receipt of the notice of termination of the Contract will be purchased by “SALAMA” under the conditions and prices of the Contract. For the remaining Goods, “SALAMA” may decide:

(a) to have any part of it produced and delivered under the conditions and prices of the Contract; and/or

(b) to cancel the remainder and pay the Holder an agreed amount in respect of the Goods partly completed and delivered.

25 − FORCE MAJEURE

25.1 The term “Force Majeure” means an event beyond the control of the Supplier, which is not attributable to its fault or negligence and which is unforeseeable. Such events may include, but are not limited to, disturbances such as wars, revolutions, quarantine measures and embargoes on freight, disasters or accidents (cyclones, floods, fires, epidemics, etc.), acts of terrorism, acts of government, lockouts, changes in market conditions, etc.

25.2 In the event of Force Majeure, the Supplier will promptly notify “SALAMA” in writing of the existence of Force Majeure and its reasons. Unless it receives instructions to the contrary from “SALAMA”, the Supplier will continue to perform its obligations under the Contract to the extent that it is reasonably possible to perform them, and will endeavour to find any other reasonable means of performing the obligations the performance of which is not hindered by the Force major.

25.3 Notwithstanding the provisions of clauses 5, 6 and 7 of the General Clauses, the Supplier shall not be exposed to the seizure of its performance bond, or to penalties, or to termination for non-performance if its delay in performing its services or other failure to fulfill its obligations in execution of the Contract is due to Force Majeure.

26 – EVALUATION OF SUPPLIERS

All facts and actions carried out by the Supplier in the execution of this contract will be evaluated and taken into account in future transactions.

The evaluation criteria are:

- Compliance with the delivery deadline

- execution of the contract

- compliance with technical specifications upon delivery

- the existence of quality/salama complaints in relation to the number of batches delivered

- the time limit for responding to complaints on regulatory matters (registration)

- compliance following post-marketing quality control

27 − REGISTRATION OF MEDICATIONS

27.1 According to the legislation in force, any medicine dispensed on the territory of Madagascar must have a Marketing Authorization (MA) issued by the Madagascar Medicines Agency. The supplier must be able to present to SALAMA a copy of the MA certificate or any document certifying that the product is accepted by the Madagascar Medicines Agency for sale on the national territory.

27.2 Any drug prequalified by SALAMA must have a valid marketing authorization at the time of awarding the contracts or, failing that, must have provided all the required documents to SALAMA. The supplier will be given a deadline to complete all the documents.

According to the Letter of Understanding between SALAMA and the Madagascar Medicines Agency relating to the registration of essential medicines entering the SALAMA circuit, the registration files required by the Registration Service in CTD format (Module 1 to 5) or the files listed below:

- 01 Summary of product characteristics (SPC) with the list and references of active raw materials and excipients with known effects;
- 01 Certified copy of the original (notarized copy) of the Good Manufacturing Practices (GMP) certificate from the manufacturing laboratory established by the competent health authority of the country and valid for at least 6 months;
- 01 Certified copy of the original (notarized copy) of the marketing authorization for the medicine issued by the competent authorities of the country of origin or, where applicable, the country of provenance;
- 01 Certified copy of the original (notarized copy) of the WHO model certificate of pharmaceutical product (COPP);
- 01 Certificate of analysis of raw materials and of the finished product of the corresponding batch
- 01 copy of the finished product control methods recommended by the manufacturer with validation in the case of In-House methods.
- 01 Real-time finished product stability study report.
- 01 complete study protocol
- 01 manufacturing license
- The model samples of sales of medicines required by the registration, with the quantities required by the procedures of the latest edition of the Madagascar Medicines Agency, the quantities to be provided of which are:
    - **Tablets and capsules in single-use packaging (blister, strip):**Three (3) secondary packaging (e.g. box of 100) intact with original label in addition to 100 units
    - **Injectable ampoules and vials:**Three (3) secondary packaging (e.g. box of 100) intact and duly labeled in addition to:
- **50 bulbs:**solutions and powders for injections
- **100 bottles:**solutions or suspensions (<5ml)
- **50 bottles:**solutions or suspensions (5ml≤ solution < 50ml)
- **20 bottles:**solutions or suspensions (50ml ≤ solution < 100ml)
- **10 bottles:**solutions or suspensions (100ml ≤solution <500ml)
- **5 bottles:**solutions ≥500 ml
    - **Solutions and ointments for external use:**Five (5) units in addition to:
- **50 tubes:**ointment and cream (mass < 5g)
- **20 tubes:**ointment and cream (5g ≤ mass ≤ 15g)
- **10 tubes:**ointment and cream (mass > 15g)

The supplier will authorize SALAMA to submit the files to AGMED.

Registration fees:

- Free for cancer patients
- 200 Euros per product. Paymentmust be made to the bank account of the Madagascar Medicines Agency below, after receipt of an invoice issued by this institution:

Madagascar Medicines Agency (EURO)

- Name of the Bank: MALGACHE BANK OF THE INDIAN OCEAN
- Account holder: MADAGASCAR MEDICATION AGENCY
- Account number: 00004 00002 07047620101 03
- BIC Code: BMOIMGMG
- IBAN code: MG4600004000020704762010103

NB: all bank charges related to transfers are your responsibility.

27.3 In all cases, the beneficiary must ensure that these medicines are registered in Madagascar at the time of loading. No unregistered medicine should be presented at the ports of disembarkation in Madagascar. Beneficiaries are advised that non-compliance with these rules seriously exposes the competent authorities to refusal of customs clearance of the goods. The SALAMA Purchasing Center cannot be held responsible for any damages resulting therefrom.

Done at ..……, on .....……. Done in Antananarivo, on .....……..

For the supplier,
(Read and approved, in handwritten letter)

The General Manager of SALAMA
Mieja Vola RAKOTONARIVO

SPECIAL CLAUSES BOOKING

A - SPECIAL ADMINISTRATIVE CLAUSES

1 − GENERAL INDICATIONS

The following special clauses will supplement the General Clauses. In all cases where the provisions contradict each other, the following provisions will prevail over those of the General Clauses.

2 − CONTRACTING AUTHORITY

This Restricted Call for Tenders is launched by:

THE CENTRAL PURCHASING OFFICE FOR ESSENTIAL MEDICINES AND MEDICAL EQUIPMENT IN MADAGASCAR, CALLED "SALAMA".

"SALAMA" is a non-profit association, with autonomous management, whose mission is to supply public health structures, as well as private non-profit training, with generic Essential Medicines and Medical Consumables appearing on the latest National List published by the Ministry of Public Health.

"SALAMA"
(Central Purchasing of Essential Medicines and Medical Equipment of Madagascar)
Lot III A 112 - Anjanamasina Anosiala - PK 18 RN 4
District Ambohidratrimo - 105 ANTANANARIVO - MADAGASCAR
Tel: 261 34 97 469 24 / 261 34 13 469 25 - Email: salama@salama.mg

3 − SUBJECT OF THE CONTRACT

The Market covers the Supply of essential medical consumables-medicines,

The quantity is shown in the quantity and unit price schedule of each supplier within the framework of this Restricted Call for Tenders document.

4 − MARKET DEFINITION

4.1. This International Call for Tender will give rise to the award of contracts with purchase orders at unit prices, for any order notified in 2025.

The contract is a unit price contract, with purchase orders for the Supplies indicated in article 3

The overall quantities to be supplied for each item, indicated in the schedule of quantities and unit prices, are given for information purposes only, and may vary from +50% to -50%.

4.2. Purchase orders will be drawn up by “SALAMA” as required. It will specify:

- The designation of each item to be delivered
- The quantities ordered for each item
- Unit prices of the products ordered
- The total amount of the order
- Manufacturer and country of origin
- The expiration date
- The total delivery time including the production, routing and delivery time to the SALAMA warehouse in Antananarivo Madagascar

4.3. Bids may be for one or more items. In this case, the bidder may indicate the discount it would grant if it were awarded all of the items.

4.4. “SALAMA” reserves the right to award the Contract, item by item, or to consider each bidder’s offer as a whole.

4.5. “SALAMA” reserves the right not to award one or more articles.

4.6. "SALAMA" reserves the right not to follow up on the International Call for Tender, nor to incur any liability whatsoever towards the tendering supplier.

5 − DURATION OF THE MARKET

The Market remains valid until delivery of the entire order to the SALAMA warehouse.

During the term of the Contract, “SALAMA” may place firm orders with the successful bidders, within the limits provided for in Article 4 of the Special Administrative Clauses, for the items for which they have been selected, at the tender prices as indicated in their tenders.

6 − PRICE SETTING PROCEDURES AND PRICE SYSTEM.

6.1 Bid Price

The unit prices for submission are understood to be: DDP SALAMA ANTANANARIVO MADAGASCAR including VAT for all Suppliers

The Prices are FIRM for the duration of the Contract defined in article 5 of the Special Administrative Clauses.

6.2 Tax regime

In the event of a change in the tax regime and/or tax rates in force in Madagascar, SALAMA reserves the right to renegotiate the Contract price with the Supplier in proportion to the new rates.

7 − PERFORMANCE GUARANTEE

7.1 For each order, within thirty (30) days of receipt of the order award letter issued by “SALAMA”, the successful Bidder must provide a Performance Guarantee equivalent to 10% of the total amount of the contract awarded.

7.2 Bank guarantee for performance for foreign suppliers and Bank check for local suppliers;

Valid for ONE YEAR, extendable.

The Bank of the successful Bidder must be a first-rate bank.

7.3 This performance bond is mandatory for any contract awarded under this Restricted Call for Tenders/Consultation and will be exempted if the amount of the contract is less than:

1500 USD or 1200 EUR for foreign suppliers

Or the equivalent in local currency MGA for local suppliers (Exchange rate on the date of order allocation)

And will be released no later than 30 (thirty) days after delivery by means of a release certificate issued by SALAMA

7.4 This deposit will be waived if the delivery time is less than 30 days.

7.5 In the event of poor performance by the supplier of its contractual obligations under the conditions set out in article 16.2 and 18 of the general administrative clauses, SALAMA reserves the full right to seize the performance bond and informs the holder at the same time.

8 – PAYMENT OF SUPPLIERS

8.1Payment terms: CHECK FOR LOCAL SUPPLIERS AND FREE DISCOUNT FOR FOREIGN SUPPLIERS

-by bank transfer to a bank located in the country of the foreign Supplier in the currency of submission, and upon presentation to SALAMA of the documents indicated in article 8.2 paragraph 8.2.1 of the special administrative clauses for the advance and article 3 paragraph 3.1 of the special technical clauses for the balance.

- by check for local suppliers upon presentation at SALAMA of the documents indicated in article 8.2 paragraph 8.2.1 and the special administrative clauses for the advance and article 3 paragraph 3.2 of the special technical clauses for the balance.

8.2 Payment conditions:

8.2.1 Payment in Advance:

The advance is provided for contracts with an amount greater than: 26,000 USD or 20,000 EUR or 90,000,000 MGA.

The advance rate is set at 30% of the contract amount.

SALAMA reserves the right to make a derogatory decision regarding the granting of an advance

Payment of the advance will be made within thirty (30) dayson presentation at the “SALAMA” level:

- the proforma invoice corresponding to the contract;
- a performance bond equivalent to 10% of the contract amount
- a bank guarantee, equivalent to 30% of the contract amount,

Bank guarantee and security deposit for foreign suppliers issued by a first-rate bank, and bank checks for local suppliers with a validity of ONE YEAR, extendable.

Payment of the balance 70% of the contract amount will be made after deduction and/or lifting of any possible reservations, within a maximum period of 60 days after delivery.

For short-lived products, split deliveries, possibility of payment after each delivery.

8.2.2 Payment without Advance: Payment will be 100% of the amount of the contract within a maximum period of 60 days against the performance bond and after deduction and/or lifting of any possible reservations.

Possibility of partial payment by invoice after each partial delivery

9 − DELIVERY TIME or PERFORMANCE TIME

Unless otherwise agreed by "SALAMA", the actual delivery time of the order must be that mentioned in the allocation slip following the supplier's offer.

Whatever the payment conditions adopted, the delivery period starts after receipt by the holder of the original letter of allocation = purchase order; justified by a discharge for local suppliers and proof of delivery of express mail (tracking on website) for foreign suppliers.

In the context of this Restricted Call for Tenders/consultation, a grace period of 10 days is granted to the successful bidder. After this period, the delivery penalty will be applied.

10 − PENALTIES FOR LATE DELIVERY

10.1 When the contractual delivery period is exceeded due to the supplier, the latter will incur, per day of delay and without prior notice,

A penalty calculated according to the following formula:

P= VXR / 1000 in which
P = Amount of penalties,
V = Penalized value (supply not delivered)
R = Number of calendar days late.

10.2 The deductible amount will be capped at 10% of the amount of the penalized value.

10.3 Regardless of late payment penalties, "SALAMA" will have the right to provide for the needs of the service at the supplier's expense and risk and may terminate the Contract in the event of excessive or repeated delays.

10.4 If the Supplier has a specific request regarding the late payment penalties applied, it must notify SALAMA by an official letter with the reasons and supporting documents for the request.

10.5 SALAMA will assess the request and reserves the right not to follow up.

11 − SETTLEMENT OF DISPUTES

11.1 Any dispute or litigation which may arise, either during the execution of the Contract or after the completion of the Contract, will, in the first instance, be settled amicably.

11.2 In the event that this procedure is unsuccessful, between "SALAMA" and the Supplier, the latter being a national of the Republic of Madagascar, the dispute or litigation will be brought before the courts of Antananarivo, sitting in commercial matters.

11.3 In the event of a dispute between "SALAMA" and the foreign Supplier, the dispute or disagreement will be settled definitively and without appeal by arbitration in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or three arbitrators. The language used will be the language of the market and Antananarivo is designated as the seat of arbitration. This clause must be specially approved by the parties.

Done at ..……, on .....…… **Done in Antananarivo, on .....……..**

For the supplier,
(Read and approved, in handwritten letter)

The General Manager of SALAMA
Mieja Vola RAKOTONARIVO

B.2. TECHNICAL CLAUSES RELATING TO THE SUPPLY

Features of the supply

1.1. TRANSPORT PACKAGING

The Supplier shall make all arrangements for packaging and wrapping to ensure that its Supplies are properly protected from damage during transport and storage. The Supplier shall be fully responsible for the quality of the packaging of the Products.

The packaging must offer the best guarantees to effectively protect the supplies during their transport to the “SALAMA” stores.

This protection concerns: general transport conditions, the specific climatic conditions of Madagascar, the specific packaging conditions required for medicines and consumables, the risks of deterioration of packaging and theft during transport.

Packaging is carried out under the responsibility of the supplier. Any packaging deemed defective upon receipt in the “SALAMA” stores will incur the supplier’s liability; in this case, the costs of returning the package will be at their expense or will be deducted from their invoice.

All crates or cartons must clearly indicate the following information:

On each package, a label of size (21 cm x 15 cm), readable from a distance of at least two meters, will indicate:

- the designation of the supply as appearing on the Price and Unit Quantity Schedule.
- the date of manufacture and expiry of the manufacturing batch
- the lot identification number
- the quantity contained in a box
- the weight of the package

A second label will specify the receiving address in Madagascar:

"SALAMA" - Central Purchasing of Essential Medicines and Medical Equipment of Madagascar

Lot III A 112 - Anjanamasina Anosiala - PK 18 RN 4

Ambohidratrimo District

105 ANTANANARIVO

MADAGASCAR

No crate or carton may contain products from different batches. These cartons or crates will be grouped on the same pallets.

Cold chain products must have a label indicating the storage temperature and the precautions to be taken:
Ex: +2 to +8°c, keep cool, heat-sensitive products, etc.
Any shipment, whether at room temperature or under cold chain, must be subject to temperature monitoring using a thermometer which records the temperature data of the data loger type shipment.

1.2 PACKAGING

The supplies delivered under the Contract will be presented in the manufacturer's original packaging and will comply with the packaging proposed during submission and award.

1.3 EXPIRATION DATE

The supplies must clearly show the date of manufacture and the expiry date (use-by date).

THE REMAINING SHELF LIFE OF THE PRODUCTS MUST BE GREATER THAN ¾ OF THEIR TOTAL SHELF LIFE FROM THE DATE OF RECEIPT IN THE SALAMA STORE.

If there are any requests for exemption from non-compliance with the remaining shelf life on the part of the supplier, he is required to request SALAMA's opinion in writing (email or letter) within three (3) days

after receipt of the Purchase Order. Otherwise, SALAMA considers the acceptance and strict compliance with the agreed expiry date.

SALAMA has the right to accept or refuse the proposal depending on the state of their stock. In case of refusal, the supplier undertakes to respect the terms of the contract and to deliver a fresh batch meeting the agreed ¾ remaining shelf life.

The Supplier must indicate in its submission whether the Supply has a short life, and must explain the reason and specify the period of validity of the Supply from its date of manufacture.

1.4 CONFORMITY OF DELIVERIES

During the execution of the Contract, conformity checks or quality checks may be carried out by "SALAMA". In the event that the products thus checked by one or more laboratories do not comply with the samples submitted, or with the required standards, "SALAMA" reserves the right to terminate the Contract of the supplier concerned without compensation. In this case, the supplier may request acounter-expertise, at its own expense, from a WHO-approved laboratory. "SALAMA" will keep the incriminated batches available to the supplier. The supplier will have a period of three months to repossess them, with the related transport costs being its responsibility. After this period, "SALAMA" reserves the right to destroy, without paying for them, the supplies deemed non-compliant. The destruction costs will be borne by the supplier and deducted from the final invoice. The pricing conditions relating to the destruction operations will be set by SALAMA (collection, transport and processing).

1.5 LABELING MODE

The labelling must be written partially or entirely in French, and must indicate:

- the name of the product under International Common Denomination,
- the dosage or number of international units, determined in relation to WHO standards.
- the applicable standard
- the name of the technique used
- the complete identification of the manufacturer and the Control Institute
- the manufacturing batch number, manufacturing and expiry date,
- any special storage conditions,
- the number of units contained in each packaging unit.

1.6 STANDARDS AND QUALITY

All supplies must:

(a) meet the requirements of the laws and regulations governing the manufacture of pharmaceutical products in the country of origin;

b) comply with all the requirements indicated in the Special Technical Clauses;

(c) be certified by a competent authority of the country of the manufacturer or Supplier in accordance with resolution 28-65B of the World Health Organization's "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce".

(d) meet the requirements of the laws and regulations governing the manufacture and marketing of pharmaceutical products, as defined by the Madagascar Medicines Agency (AGMED).

1.7 Products under cold chain - Low temperature storage

With regard to supplies requiring low temperature storage (refrigerator or freezer), the Supplier will take, from the point of embarkation to the place of actual delivery, according to the conditions described in articles 1.1 of the Special Technical Clauses, all transport arrangements in order to transport these supplies in the perfect conditions required to ensure the continuity of the cold chain.

All products, including those under the cold chain, must be accompanied inside each package and during transport from the manufacturing site to SALAMA's stores, by an automatic temperature recording device, so that SALAMA can access the temperature data upon receipt of the goods.

The supplier is required to bear the costs of storing the products in a cold room under customs control.

1.8 Delivery conditions:

The following products will be delivered by air if their successful bidders are foreign suppliers

DESIGNATION
Phytomenadione (vit K1) 10 mg/ml amp 1ml
Regular insulin 100 IU/ML inj FL/10 ml

Intermediate insulin 100 IU / ml inj FL 10ml
Pancuronium Bromide 2 mg / ml inj – amp -
Injectable Anti-Tetanus Serum
Phenobarbital 40 mg/ml amp of 1 ml
Fentanyl 50µg/ml amp of 2ml
Fentanyl 50µg/ml amp of 10 ml
Ergometrine maleate 0.5 mg/ml inj 1ml – amp
Suture threads
Epinephrine Adrenaline INJ - amp

1.9 Products placed under international control

For the following items, the Supplier must be authorized by the competent Authorities of its country to export these products. "SALAMA" will obtain the import authorization from the Directorate of Pharmacy, Laboratory and Traditional Medicine (DPLMT) – and will send it to the Supplier.

Information on the basic weight of each product will be provided by the supplier.

Costs related to sending the documents will be charged to the supplier.

DESIGNATION	STATUTES
Diazepam 5 mg cp (blister)	(b)
Diazepam 5 mg/ 2ml – Inj -	(b)
Ergotamine-caffeine 1mg-100mg – tab -	(c)
Ergometrine maleate 0.5 mg – tab -	(c)
Ergometrine maleate 0.5 mg/ml amp 1ml	(c)
Fentanyl 100 µg/2ml amp inj 2ml	(has)
Fentanyl 500 µg/2ml amp inj 2ml	(has)
Phenobarbital 50 mg tablet (blister)	(b)
Phenobarbital 40 mg/ml inj	(b)
Morphine Hcl 10 mg/ml inj	(has)
Morphine 10 mg LP-cp	(has)
Morphine 30 mg LP-cp	(has)
Potassium permanganate 0.5 g – tab -	(c)
Nalbuphine 10mg/ml amp inj	(has)
Oxycodone 5mg cp	(has)
Pethidine 100mg/2ml amp inj	(has)
Hydromorphone LP 4mg gelu	(has)

Delivery of these products must be made in accordance with:

(a)- the Single Convention on Narcotic Drugs of 1962

(b)- the 1971 Convention on Psychotropic Substances

(c)- the Convention against Illicit Traffic in Narcotic Drugs

2. PACKAGING

In addition to the information described in article 1.2 of the Special Technical Clauses, each package delivered will be numbered and must imperatively include, under penalty of refusal of the goods, the following information:

- supplier name
- order number,
- corresponding delivery note number,
- number of units of each item

3 – PAYMENT AND DELIVERY DOCUMENTS

3.1 Payment documents

- Detailed commercial invoice in FOB PER ITEM, FREIGHT-INSURANCE, mentioning the manufacturers, countries of origin, expiration dates, and batch numbers of each product

- Copy of Bill of Lading or Air Waybill (AWB)
- Copy of expert report

- Copy of the proof of residence
- Copy Packing List
- Physical control and packaging control sheet

The information that should be included on this list is as follows:

•the order number of “SALAMA”
•the unit quantities of each item shipped,
•the number of packages for each product shipped,
•the total weight and total volume of the delivery,
•for products requiring cool storage, the corresponding volume.

- Cargo Tracking Note (CTS) Acceptable: SGS inspection is no longer required but you should register the shipment on the sitewww.bscmg.sgs.com
SALAMA's ID number is 5497
Contact Technical Center:MG.BSC@sgs.com
- Contact the supplier's freight forwarder in charge of customs clearance at the port or airport of disembarkation in Madagascar
- Any storage and/or demurrage costs incurred due to delays in customs clearance at the port or airport of disembarkation in Madagascar by the supplier will be borne by the supplier.

For local suppliers:

- Commercial invoices
- Delivery note
- Physical control and packaging control sheet

3.2 Customs clearance authorization for Medicines:

The supplier must ensure that the medicines are registered with the Madagascar Medicines Agency and send SALAMA the valid registration certificates before shipping the goods.

No shipment of medications should be carried out without a marketing authorization certificate.

Failure to comply with these rules may result in refusal of customs clearance of goods by the competent authorities. The SALAMA Purchasing Center cannot be held responsible for any damages resulting from this.

The request for authorization for customs clearance of Medicines under the MIDAC module will be made by SALAMA upon receipt of the final commercial invoice from the supplier, detailing FOB PRICE PER ITEM, FREIGHT COST, INSURANCE, and mentioning the NAMES OF THE MANUFACTURERS, the BATCH NUMBERS of the medicines delivered.

The approved Customs Clearance Authorization will be forwarded to the Supplier's Freight Forwarder by Salama

Any storage and/or demurrage costs incurred due to the delay in approving the customs clearance authorization will be borne by the supplier.

3.3 Delivery documents:

The supplier must attach to each delivery:

- Certificate of analysis for each batch of items delivered (mandatory before any receipt)
- Certificate of origin of products
- Certificate of sterility for sterile consumables
- Delivery note: two originals

Each delivery will be accompanied by a delivery slip which will indicate, for each package:

- the order number of “SALAMA”,
- the number of units contained in the delivery for each item,
- the item number,
- the designation of each item,
- the price per item,
- the total quantity delivered
- the total price of delivery.

4 – CONTROL AND ADMISSION

4.1 RECEPTION

Before shipping, any goods subject to registration must have the approval of the artwork and the notice by the Quality Assurance Department. Photos and videos of the products must be provided before shipping. The reception by "SALAMA" consists of checking the conformity in quantity and quality (according to the sample provided and validated) of the items delivered with the requirements of the specifications of this call for tender. "SALAMA" will have a period of 30 (thirty) days from the day after the date of receipt in its stores, to quantitatively accept the supplies and a period of 60 (sixty days) from the day after the date of receipt in its stores, to qualitatively accept the supplies. The availability of the COA is mandatory upon physical receipt (electronic sending / physical sending).

Salama Office and Store Opening Hours: 7:30 a.m. to 3:45 p.m. (local time)

4.2 DAMAGED AND MISSING

In the event of damage or possible shortage noted by an approved expert, affecting supplies, “SALAMA” will deduct the amount of the damaged or missing goods from the commercial invoice.

In the event that the amount of damaged or missing goods reaches more than 25% of the amount of the delivery, the Supplier will be required to replace the defective or missing supplies within one month, by air delivery (if foreign supplier). All costs relating to this new delivery (freight, insurance, customs duties, taxes, approach costs) will be borne by the supplier.

4.3 REPLACEMENT OF NON-CONFORMING SUPPLIES

In the event of non-conformity of the supplies delivered with respect to the Contract, noted by an authorized expert, the Supplier will be required to replace the defective supplies within one month, by air delivery (if foreign supplier). All costs relating to this new delivery (freight, insurance, customs duties, taxes, approach costs) will be borne by the supplier.

4.4 POSITIVE QUALITY CONTROL

“SALAMA” may at any time carry out a quality control of the products with an independent laboratory of its choice. The costs relating to the quality control will be borne by “SALAMA”.

If, following the inspection, the products are found to be non-compliant, "SALAMA" will notify the supplier in writing. The supplier may request a counter-expertise at its own expense from a laboratory approved by the WHO. "SALAMA" reserves the right to inform the supervisory authorities, as well as the services responsible for the WHO Certification Scheme in the event of serious problems.

The Supplier shall be required to replace non-compliant Supplies within one month.

If the non-compliant Supplies are not recovered within 60 (sixty days) by the supplier and at its expense, they will be destroyed by “SALAMA”. The destruction costs will be borne by the supplier and deducted from the final invoice. The pricing conditions relating to the destruction operations will be set by SALAMA (collection, transport and processing)

4.5 TECHNICAL CONDITIONS OF ACCEPTABILITY

In conclusion, to avoid any inconvenience due to the refusal to receive the delivered products and their payment, each supplier is required to respect:

- The required expiration date
- Completeness and conformity of documents upon delivery (certificate of analysis for each batch)
- Delivery time

4.6 NON-COMPLIANCE FOUND FOLLOWING A QUALITY COMPLAINT

Following a quality complaint, SALAMA may at any time recall a batch of non-compliant products, informing the supplier at the same time.

The supplier is required to provide an explanation and an action plan following a proven quality complaint (confirmed by laboratory analysis); each complaint must be communicated by SALAMA to the supplier and must be closed within a reasonable time.

SALAMA reserves the right not to request a replacement of the goods, but to deduct the full amount of the batch concerned from the supplier's invoice payments, and cannot be required to reimburse the amount of non-compliant products not returned by customers.

If the non-conforming goods are not collected within 60 days (sixty days) by the supplier at its own expense, they will be destroyed by SALAMA. The costs of destruction will be borne by the supplier. The costs of destruction will be borne by the supplier and will be deducted from current or future invoices.

In the event of a proven complaint, an investigation will be carried out beforehand by SALAMA and shared with the supplier with all the information justifying the non-conformity (quantity concerned, photos, etc.), the supplier undertakes to respond within a maximum of 5 working days.

This response time may be reduced in the event of non-compliance depending on the level of criticality of the dispute.

In the event of an anomaly or recurring non-conformity, a financial package will be requested by SALAMA to compensate for the damage and the stock shortage that this could cause.

4.7 SUSPENSION OF AMM OR PROBLEMS INHERENT TO PHARMACOVIGILANCE

Following a refusal or suspension or cancellation of MA, notified by the National Regulatory Authority, or following any problem related to pharmacovigilance or any other decision notified by the competent authorities of the country, SALAMA will proceed to the immediate quarantine of the products concerned and the recall of the batches in circulation. The removal or destruction of the products will be at the supplier's expense. SALAMA reserves the right to deduct the full amount of the batch concerned from the supplier's invoice payments, and cannot be required to reimburse the amount of non-compliant products not returned by customers.

Article 5:*Approval*

The parties to the contract have signed this Contract in accordance with the law of the country of SALAMA, on the days, months and years mentioned below.

Done at ..……, on .....…….. **Done in Antananarivo, on .....……..**

For the supplier ,
(Read and approved, in handwritten letter)

The General Manager of SALAMA
Mieja Vola RAKOTONARIVO

CERTIFICATE OF NOTIFICATION

This day,....., I, the undersigned, Mieja Vola RAKOTONARIVO, General Manager of SALAMA, certify having notified ……. of contract no…… of ……., concerning the supply of ……...

Done in Antananarivo, on

_____

Mieja Vola RAKOTONARIVO

GENERAL MANAGER

Appendix No. 5: SUPPLIER EVALUATION GRID MODEL

SERVICE APPROVISIONNEMENT / SERVICE ASSURANCE QUALITE

Salama

FICHE D'EVALUATION FOURNISSEUR ANNEE …..

Date:	Evaluation n°:
Nom de l'évaluateur côté Approvisionnement:	Fonction:
Nom de l'évaluateur côté Assurance Qualité:	Fonction:
Marché évalué:	

INFORMATIONS SUR LE FOURNISSEUR

Nom de l'entreprise:		
Adresse de l'entreprise:		
Téléphone:		Email:
Nom du dirigeant:		Email du dirigeant:
Nom de l'interlocuteur:	Email de l'interlocuteur:	Poste de l'interlocuteur:
Types produits:		
Statut du fournisseur (Local/Etranger):		
Statut de production (Fabricants/Grossiste):		

EVALUATION DU FOURNISSEUR

CRITERES	NOTE		PONDERATION	NOTE AVEC PONDERATION
1. DELAI DE LIVRAISON /5pts Conformité à 100%: 05 pts Conformité [90-99%]: 4 pts Conformité [80-89%]: 3 pts Conformité [70-79%]: 2 pts Conformité [<70%]: 0 pt			20%	
2. EXECUTION DU MARCHE (DESISTEMENT)/5pts Désistement 0: 5 pts Désistement [1-25%]: 2,5 pts Désistement > 25%: 0 pts			15%	
3. CONFORMITES AUX SPECIFICATIONS TECHNIQUES/5pts SANS NC: 5pts Existence d'au moin 1 NC: 0pts			20%	
4. Existence de réclamation client/SALAMA/5pts Sans réclamation: 5 pts Existence de réclamation SALAMA: 2,5 pts Existence d'au moins 1 réclamation client: 0 pt			15%	
5. REPONSES AUX RECLAMATIONS QUALITE ET ENREGISTREMENT/5pts Réponse satisfaisante/ sans réclamation: 5 pts Réponse moyennement satisfaisante (délai et type): 2,5 pts			10%	
6.CONTROLE QUALITE POST MARKETING/5pts Sans NC: 5 pts Existence de réclamation SALAMA: 2,5 pts Existence d'au moins 1 réclamation client: 0 pt			20%	
TOTAL		/30		/100%

RESULTAT

NOTE	QUALIFICATION	MESURES
80-100%	SATISFAISANT	INTEGRATION EN TANT QUE PARTENAIRE STRATEGIQUE
50-80%	MOYENNEMENT SATISFAISANT	REMERCIEMENTS ET ENCOURAGEMENTS
<50	NON SATISFAISANT	AVERTISSEMENTS

Si + 3 AVERTISSEMENTS = écartement pour une période de 1 an

En cas de marché en cours, engagement sur l'amélioration des performances pour ces marchés et sur les critères évalués (délais, qualité, desistement….)

Evaluateur APPRO	Evaluateur QUALITE
Responsable Approvisionnement IS	Pharmacien Responsable
Directeur des Approvisionnements et Stocks	

Appendix No. 6: MANUFACTURER'S AUTHORIZATION MODEL

To: SALAMA Central Purchasing Office for Essential Medicines of Madagascar

WHEREAS[Manufacturer name], established and recognized manufacturer of [name and/or description of supplies], having our factories at [factory address], hereby authorize [Agent name and address] to submit an offer, and subsequently to negotiate and sign a Contract with you under the International Call for Tenders AOI 1/25for the above-mentioned supplies manufactured by us.

We hereby extend our full warranty, in accordance with the provisions offered by the said company in response to this International Call for Tender.

_____

[signature for and on behalf of the Manufacturer]

Note : This letter of authorization must be written on paper in-Manufacturer's head and be signed by a person duly authorized to sign documents binding on the Manufacturer. It must be attached by the Bidder to its offer.

Appendix No. 7: MODEL REPRESENTATION FORM

Mr. or Mrs.: ……

Acting as (1): ……..

Company : ……..

Address : …….

By this mandate, give power to:

Mr. or Mrs.: ……

Acting as (2): ……..

Address : …….

To represent the company at the opening session of the International Call for Tenders AOI 1/25, taking place on 'Wednesday April 30, 2025 at 9:00 a.m at the headquarters of:

SALAMA Central Purchasing Agency for Essential Medicines and Medical Equipment of Madagascar

Lot III A 112 - Anjanamasina Anosiala - PK 18 RN 4

District Ambohidratrimo - 105 ANTANANARIVO - MADAGASCAR

Done at ……..on,

Name, signature and stamp of the company

a. Indicate the function of the signer
b. Indicate the representative's function

NB: document to be placed on company letterhead and presented to attend the tender opening session

Appendix No. 8: TEMPLATE ALLOCATION FORM

INTERNATIONAL CALL FOR TENDER AOI 1/25

AWARD OF CONTRACT AOI1/25/...A (Name of Supplier)

ITEM N°	DESIGNATION	CONDT	UNIT QUANTITY	DDP SALAMA UNIT PRICE in (MONETARY UNIT)	AMOUNT DDP SALAMA in (MONETARY UNIT)	MANUFACTURER	COUNTRY OF ORIGIN	FULL ADDRESS OF THE MANUFACTURER'S WEBSITE	EXPIRY DATE	PRODUCTION TIME	DELIVERY TIME	TOTAL DELIVERY TIME

TOTAL MARKET C3/24/...A (Supplier Name) **MONETARY UNIT**

INCOTERM:

PAYMENT CONDITION:

100% within 60 days from the date of delivery of the goods against a performance bond equal to 10% of the contract amount or 30% in advance against an equivalent bank guarantee and a performance bond equal to 10% of the contract amount, and 70% within 60 days from the date of receipt of goods

Appendix No. 9: NON-EXHAUSTIVE LIST OF PRODUCTS TO BE STORED BETWEEN +2°C TO +8°C

DESIGNATION
ZOLEDRONIC ACID 4LMG/5ML INJ
ALANINE AMINOTRANSFERASE (ALAT)
ALSO (with Glucine NaCl Buffer)
ANTI A 26A2 Mono NF INT
ANTI A+B
ANTI B 95.3 Mono NF INT
ANTI B Lot N°2
ANTI D Mono NF
ANTI DCE (RH1,2,3) Monoclonal
ANTIA+B Mono TRI NF
ASPARATATE AMINOTRANSFERASE (ASAT)
BLEOMYCINE 15MG INJ
CEFEPIME 30µG discs
CRP LATEX TESTS
DACARBAZINE 200MG INJ
DOCETAXEL 20MG INJ
DOCETAXEL 80MG INJ
DOXORUBICIN 10MG INJ
DOXORUBICIN 50MG INJ
EBV ELISA TESTS
EPIRUBICIN 10MG INJ
ERGOMETRINE MALEATE 0.5MG/ML INJ
ERGOMETRINE MALEATE 5MG
CALCIUM FOLINATE 50MG INJ
GAMMA - GLUTAMYL TRANSFERASE (GGT)
GLUCOSE 4*100ML
HCV B/36TESTS
INSULIN HUMAN BASAL 100UI/ML INJ
HUMAN INSULIN RAPID 100IU/ML INJ
INTERMEDIATE INSULIN (MIXTARD) 100UI/ML INJ
REGULAR INSULIN (ACTRAPIDE) 10IU/ML INJ
OXYTOCIN 10IU/ML INJ
PANCURONIUM BROMIDE 2MG/ML IN
TOTAL PROTEIN
RHESUS CONTROL
RPR TESTS
ANTITETANIC SERUM 1500UI INJ
TETRACOSACTIDE 0.25MG SOL INJ
TETRACOSACTIDE 1MG SOL INJ
TPHA B/100 TESTS
TRIGLYCERIDES
VINBLASTINE 10MG INJ
VINCRISTINE 1MG INJ FLC 1ML

SALAMA purchasing center
Medicines in bold

Appendix No. 10: LIST OF FREIGHT FORWARDERS

Forwarding agent	ADDRESS	CONTACT	SUCH	E-MAIL
FTL Madagascar	**R+3,3rd Floor, New NY Havana Building - Ankorondrano Games Village**	Mr ALEXANDRE MALHEIRO	22 548 00	**fanja.douane@ftlmada.mg / air1.expl@ftlmada.mg / fff@forwarderfastfinder.com / tahiana.ccial@ftlmada.mg / amalheiro@ftlmada.mg**
DAMCO LOGISTICS MADAGASCAR	**LOT VP26Ter QT ANKADIVORY AMBOHIMIANDRA**	Mr Anthony RABIBISOA	22 638 34	**anthony.rabibisoa@damco.com / haingo.andriamahazo@damco.com / hanitra.Ratsimbazafy@damco.com / tsiky.andriamitahirizosifahafahana@damco.com**
PRIMEX Logistics	**47 rue Pasteur Rabary Ankadivato**	Mr Aina RAJAONARISON	24 240 75	**operations.primex@gmail.com / lea.primex@blueline.mg**
ASL MADAGASCAR	**Building 37, AFRIPORT – ZI FORELLO Tanjombato**	Mrs. Lova RAKOTONIRINA	22 557 30	**aslcustserv@blueline.mg / aslocean@blueline.mg**
ARIVA LOGISTICS Madagascar	**Lot 039 E Bis, 2nd Floor Ambihibao**			**todisoa.mdg@ariva-logistics.com**
VIP Logistics	**Room 33 Building 2 - Cap 3000 Andraharo**		033 07 100 50	**+261 20 23 320 09 / 033 15 100 51**
PRESCOI SARL	**Point Pacom Enclosure Road Dike RN 58a Andranomena**	Mrs Zuffour Mialitiana	22 483 17/22 455 79	**prescoitnr@prescoi.com**
STTE Madagascar Logistics	**Plot 20, Forrello Tanjombato Zone**	Mrs. Soraya BOUJARD	22 572 92	**commercial.stte@ettrrat.mg / s.boujard@ettrrat.mg**
AUXIMAD	**18 rue JJ Rabearivelo Antsahavola**	Mr Lalaina RATSIRAHONANA	22 225 02	**auximad@auximad.mg / auxidc@auximad.mg / auxivato@auximad.mg / auxidc.dir@auximad.mg**
BKG	**Shoprite Building 1st Floor Ampasanimalo**		22 317 83 / 033 14 076 42	**boni@bkgholding.com**
EXPEDITORS MADAGASCAR SARL	**Housing estate Lone Ankeniheny Tanjombato**		22 571 31	**jean.bosco.rasoloniaina@expeditors.com**

DHL Global Forwarding	**DHL Hydrocarbons Road Building Akorondrano**		22 428 33	**cs.dgfmg@dhl.com**;jeanmarc.randriasamimanana@dhl.com hoby.tinasoa@dhl.com Miora.Ranaivo@dhl.com Tim.Luyckx@dhl.com stephanie.raveloson@dhl.com
Celero Madagascar SARL	1st Floor Glass BuildingLot IVF 4, Fitroafana Talatamaty IvatoAntananarivo 105, Republic of Madagascar	**Miora RANIVOHARISOA Customer Service Officer**	+261 38 59 285 46	miorar@celerogroup.comsarindrar @ celerogroup.comnathaliaa@celerogroup.com
AGL	ZI Forello – BP. 514 - Tanjombato101 - Antananarivo – MADAGASCAR	**Mr Romuald**	+261 20 22 578 24	patrick-herimalala.andrianirina@aglgroup.com gaston-roger.hajamahery@aglgroup.comromuald.ramahenina @ aglgroup.compaquerette.manjaka@aglgroup.com
THE SCANDINAVELA SEAL LINE	2 rue Lieutenant Bérard, BP 18Tamatave 501 - Madagascar	LEOPOLD	+261 20.76.325.48 - +261 20.76.325.69	sealtmm@seal.mgtransittmm @ seal.mgsealex@seal.mghasina.sealex @seal.mg
ATI		Mr RADO ROBSON	020 76 661 47	rado.robson@ati.mgservice.import @ ati.mgimport@ati.mgimport2 @ati.mg
MIDEX MADAGASCAR	**GALAXY ANDRAHARO Zone**	Mrs. ANITA ERICA	261 342 326 335	bsc@midexmada.commidac @ midexmada.comrespops@ midexmada.comrespops @midexmada.com

Appendix No. 11: MEDICATION INFORMATION SHEET

PleasefillAformseparatedForeachproduct

Section 1: Administrative section

1.1 Product identification

1.1.1Active ingredient(s) (use INN if applicable):

1.1.2Generic product name:

1.1.3Trade name (trademark) (if applicable):

1.1.4Galenic form

☐ Tablets ☐ Capsules
☐ injectables ☐ Oral syrups / suspensions
☐ Other

1.1.5Dosage per unit dose:

1.1.6Mode of administration

☐ oral ☐ IM
☐ IV ☐ SC
☐ Other (please specify)

1.1.7Please provide the product formulation (Full qualitative and quantitative composition, including active ingredient(s), overdose, if applicable, and excipients). Please also indicate the pharmacopoeia of reference for each constituent (e.g. British Pharmacopoeia, United States Pharmacopoeia, "In House"). Specifically state whether these are fixed-dose combinations of products or preparations presented in the same packaging: Appendix A

1.1.8Please indicate the inactive constituents (excipients) of medical/pharmaceutical interest, their quantity per dosage form or per unit of dosage (e.g., alcohol content 10%, paraben, etc.)

1.2Packaging

1.2.1Description of the primary packaging, its size (quantity of taking units per packaging) and the materials used: Appendix B

Please attach a certificate of analysis of the available packaging materials: Appendix C

1.2.2 Description of secondary packaging, its size and materials used: Appendix D

Please attach a certificate of analysis of the available packaging materials. Please give us an explanation of the relevance of the material choices and the compatibility of the materials with the active ingredient: Appendix E

1.3 Product Manufacturer

Manufacturer (name, address and activities) and manufacturing site(s) (or contract manufacturer(s)):

Name of manufacturer, contract manufacturer, if applicable	Reference to manufacturing authorization, date of grant and expiry date, if applicable	Physical address. Please specify- be	Telephone, fax and email number	Activity (eg. conditioning)

Attach the results of studies relating to complete pharmaceutical development.

1.4 Supplier (to be completed if the data is different from 1.3)

Company Name _____

Physical address (full contact details required) _____

_____

Phone number_____

Fax _____

Website _____

E-mail _____

Link to the product

- ☐ Marketing Authorization Holder
- ☐ Manufacturer
- ☐ Distributor / Wholesaler
- ☐ Other

1.5 Note to the bidder

Please note that the information contained in this questionnaire may be shared confidentially between ICRC, MSF, WHO Supply Hub, UNFPA and UNICEF for procurement purposes. If you have any objection, please report it to the Supply Agency you are in contact with.

Has this file been submitted to any of the following institutions: Expert Review Panel (ERP), ICRC, MSF, WHO Supply Hub, UNFPA and UNICEF?

Please indicate the date of the request _____

1.6 Regulatory situation

1.6.1 In the country of production

☐ Registered product currently on the market

Registration number (AMM) _____

Attach a copy in Appendix D

☐ Registered product authorized for sale in the country of production but currently not marketed

Registration No. _____

☐ Product registered for export only

Registration No. _____

☐ Unregistered product (please specify)

_____

• Please attach the Certificate of Pharmaceutical Product (CPP) compliant with the WHO Certification Scheme on the Quality of Pharmaceutical Substances (WHO Technical Report Series, No. 863 in Annex E.

• If it is not possible to obtain a CPP from the national medicines regulatory authorities, please indicate the reason and send an equivalent document, if available.

• Attach in Annex F letters issued recently or previously by the WHO prequalification programme/strict drug regulatory authority regarding deficiencies in the specific product dossier

1.6.2 In other countries

Provide a list of other countries in which the product is approved and currently on the market (please provide the registration number)

_____

_____

1.6.3 WHO prequalification status, if applicable

This product is prequalified by the WHO prequalification program.

☐ YES ☐ NO

If yes, please attach a copy of the corresponding WHO Prequalification Program Acceptance Letter signed by your company (Annex G).

1.6.4 Submitted for prequalification: Indicate the date of submission, the WHO acceptance letter after review of the product dossier mentioning the WHO reference number assigned by the organization to this specific product. Annex H

_____

1.7 Samples for technical evaluation

1.7.1 Finished product samples and instructions

You are requested to provide a sample of the proposed finished product(s) and the corresponding leaflets. (If you are unable to submit any of the above items with the questionnaire, please indicate why and when you will do so. (Annex I)

1.7.2 Label language (attach a copy): primary packaging

☐ Bilingual English/French ☐ French ☐ English

☐ Other (specify)

Label language (attach a copy): secondary packaging

☐ Bilingual English/French ☐ French ☐ English

☐ Other (specify)

In the case of powder for preparation of oral suspensions and for injections, the periods of validity and the storage conditions after reconstitution must be indicated on the product label.

Patient information leaflet (Appendix J)

☐ YES ☐ NO

Proposed Restrictions on Sale:

Classification in the list of narcotics

Restricted prescription or distribution

On medical prescription

In pharmacies only

Without prescription

Section 2:Raw materials

(If there is more than one active ingredient or more than one source is used, please duplicate this section)

2.1.Raw material(s) for the active ingredient(s):

Identification of the active ingredient used (INN, if applicable):

2.1.1Manufacturer

Name, physical address and country/manufacturing site (please list all other possible sources):

GMP certificate from the country of origin: attach a copy in Annex K.

Last inspection of the active ingredient manufacturing sites carried out, if applicable (please attach a GMP certificate or a letter relating to it) by:

☐ Finished product manufacturer

☐ WHO Prequalification Programme, Geneva

☐ European Directorate for the Quality of Medicines (EDQM)

☐ Food and Drug Administration (FDA) United States

☐ Members of the cooperation scheme in the field of pharmaceutical inspection (PIC/S)

☐ Others (specify)

☐ None of these

Results and date:

Have the active ingredient(s) used in the manufacture of this product been prequalified by WHO?

☐ YES ☐ NO

2.1.2 Active ingredient specifications

☐ British Pharmacopoeia (BP) (edition/year):

☐ United States Pharmacopoeia (USP) (edition/year):

☐ International Pharmacopoeia (Ph.Int) (edition/year):

☐ Others (specify):

_____

Additional specifications to those of the pharmacopoeia referenced above, if applicable

☐ YES ☐ NO

• Attach in Annex L a copy of the internal specifications of the active ingredient(s) indicated by the manufacturer of the finished pharmaceutical product

• If these are internal analytical methods, different from those of BP, USP and Ph Int, attach a copy of the method and analytical validation data in Appendix M

In the case of a sterile active ingredient:

• Please provide data on the validation of the aseptic manufacturing processes of the product including recent aseptic validation data by the media fill test, if applicable, in Appendix N.

Describe the sterilization method used, if appropriate:

_____

_____

_____

2.1.3 Certificate of analysis

Please provide a copy of the certificate of analysis of the active ingredient provided by the manufacturer of the active ingredient and a copy of the certificate provided by the manufacturer of the finished pharmaceutical product (Annex O).

2.1.4 Relevance of the monograph relating to the active ingredient

Do you have the following information regarding the active ingredients?

Certificate of conformity to the monograph of the European Pharmacopoeia (CEP):

Please attach a copy of the CEP and its annexes (Annex P).

Certificate No.: _____

2.1.5 Open part of the file (Drug master File) registered in (country):

_____

_____

_____

Technical File (please attach):

☐ YES ☐ NO

Is the active ingredient synthesized from other ingredients??

Yes or no
If yes, attach the complete and consistent list of materials used in the manufacture of the active ingredient with the process steps. Indicate where each material is used.
Are data on active ingredient stability studies available?
Please provide the protocol and report for the accelerated and long-term stability studies, including: container type and materials; conditions (temperature/relative humidity/duration of stability study); number of batches tested in the study (minimum three); batch sizes for each batch tested; study start date; and study conclusions. (This information may be provided in the Appendix…)
Raw material(s) for the excipient(s):

No.	SUBSTANCE	REFERENCE STANDARD WITH ITS EDITION	QUANTITY/ML OR MG OR UNIT	QUANTITY PER BATCH	FUNCTION

Manufacturer(s)

No.	MANUFACTURER NAME	SITE ADDRESS	GMP CERTIFICATE NO.	BPF ISSUING AUTHORITY

Manufacturer's GMP certificate: attach a copy in the appendix…
Attach in the appendix … a copy of the internal specifications of the raw material(s) by the manufacturer of the finished product
If these are internal analytical methods, different from those of BP, USP and Ph Int, attach a copy of the method and analytical validation data in the appendix.
Certificate of analysis
Please provide a copy of the certificate of analysis of the excipient(s) provided by the manufacturer thereof as well as a copy of the certificate provided by the manufacturer of the finished pharmaceutical product. If these are internal analytical methods (In house), different from those of BP, USP, and Ph.Int, attach a copy of the analytical method and the corresponding validation data in the same Annex …
Origin of raw materials
Does the finished pharmaceutical product contain raw materials of animal origin?
Yes or no
If yes, attach the TSE/BSE declaration certificate
Provide data on impurities actually present in raw materials with results

Section 3: Finished Pharmaceutical Product

3.1 Manufacturing site compliance with GMP

Inspections carried out by a national medicines regulatory authority

	Regulatory authority of the country of origin	Further inspection by a PIC/S member
BPF certificate number		
Valid until		
Country		

Please attach recent/valid GMP certificates/letter (Annexes Q)

Other inspections carried out by (attach relevant information):

Organization	Audit Date	Result
WHO Prequalification Programme		
UNICEF Supply Division		
MSF International		
ICRC		
Other (specify)		

3.2 Specification of the finished pharmaceutical product.

Reference	Edition	Year of publication
BP		
USP		
Ph. Int.		
In-house		
Additional specifications		
Other (specify)		

Please attach copies of the lot release and end-of-life (for stability studies) specifications for the finished drug product. If these are in-house analytical methods, different from those of BP, USP, and Ph.Int, attach a copy of the analytical method and corresponding validation data in the same Appendix R.

Please attach a copy of the certificate of analysis of the last three batches released in Appendix S.

3.3 Manufacturing method and process validation

Have the manufacturing methods been validated for each standard batch size?

☐ YES ☐ NO

If no, please explain:

_____

_____

_____

If yes, please specify the validation status in the table below:

The batch size of the validated batches	
Batch numbers of validated batches	
The manufacturing dates of the validated batches	
Process Validation Report Reference Number	
If processes still need to be validated, indicate the reference number of the process validation protocol	

Provide formulas for all proposed lot sizes:

Please provide in Appendix T a flow chart and description of the manufacturing and control process of this product with the corresponding parameters.
Please provide a list of materials used in the manufacture of the active ingredient with the process steps where each material is used.
Excipient
If the finished pharmaceutical product contains excipients not covered by a monograph in an existing pharmacopoeia, please provide full details of its manufacture and safety data relating to its use in Annex…
Impurity and contaminations
Provide tests for the determination of fungal and microbial contamination, search for toxic metals and contaminants (pesticides) for the case of excipients of plant origin (for liquids)
Provide complete data on potential impurities that may be introduced during synthesis, purification and storage.
Provide comprehensive data on the impurities actually present with analysis results of the actual impurity levels detected.
Provide the methods used for the determination, detection or control of impurities.
Provide complete data on impurity acceptance criteria.

3.3.1 Additional information for sterile products

• Provide data relating to the validation of the aseptic manufacturing processes of the product including recent aseptic validation data by the media fill test, if applicable in Appendix U.

• Describe the sterilization method used, if applicable:

3.4 Stability of the finished product

3.4.1 Are stability study data available?

☐ YES ☐ NO

Please provide the protocol and report for the accelerated and long-term stability studies, including: container type and materials; conditions (temperature/relative humidity/duration of stability study); number of batches tested in the study (minimum three); batch sizes for each batch tested; date of commencement of the study; and conclusions of the study. (This information may be provided in Appendix V.)

3.4.2 Have the stability studies been carried out on a product of identical formula and source of active ingredient, manufactured at the same site and packaged in the same equipment as the product which will be supplied?

☐ YES ☐ NO

If not, describe the differences:

3.4.3 Please specify whether stability studies have been carried out or are in progress with all declared Sources of active ingredient:

☐ YES ☐ NO

Submit in Appendix W a statement that stability studies have been conducted or are being conducted with all declared active ingredient sources.

If not, explain why:

_____

3.4.4 Do you have any data on ongoing stability studies on this product?

☐ YES ☐ NO

Attach the status report of ongoing stability studies in Appendix X.

3.4.5 Shelf life indicated on the packaging:

☐ 2 years ☐ 3 years

☐ 4 years ☐ 5 years

☐ Other (please specify): _____

3.4.6 Specific storage conditions for this product as indicated on the packaging and based on stability studies (e.g., “do not store above 30°C - keep away from light”):

Temperature	
Light	
Humidity	
Other (specify)	

3.4.7 Product usable in:

☐ Zone I

☐ Zone II

☐ Zone III

☐ Zone IVa

☐ Zone IVb

☐ Other (please specify): _____

3.4.8 In the case of powder for preparation of oral suspension and powder for injection, or solution for injection (possibly after dilution), or multi-dose containers, please provide in Annex Y data on in-use stability and storage conditions after reconstitution and/or dilution.

Ø Indicate the maximum duration (hours/days) during which the product is stable after reconstitution and/or dilution based on available in-use stability data:

_____

Section 4: Safety/efficacy and/or therapeutic equivalence

(WHO Technical Report Series (TRS), No. 902, Annex 11/TRS No. 937, Annex 7 or later report)

4.1 Innovative products

Please attach a summary of the pharmacology, toxicology and efficacy of the product in Appendix Z.

4.2 Generics: therapeutic equivalence

☐ Demonstrated

☐ Not demonstrated

☐ Not applicable, please explain why: _____

_____

If equivalence is demonstrated

4.2.1 By in vivo bioequivalence studies

Study period (dd/mm/yy) of _____ has _____

Reference product:

Generic name	
Dosage form	
Dosage	
Trade name	
Manufacturer	
Manufacturing site	
Lot number	
Expiration date	

Attach a certificate of analysis of the reference product conforming to the specifications

Study protocol

Name of Contract Research Organization (CRO)	
Country of study	
Number of volunteers	
Study Design (Detailed Descriptions)	

Batch sizes used for bioequivalence studies	
Number of batches used for bioequivalence studies	
Source(s) of the active ingredient(s) of the batches used for the bioequivalence studies	

Please attach the bioequivalence study report
Study results:

Conclusions of the study:

4.2.2 By comparative in vitro dissolution tests under the conditions described in the WHO document on the Biopharmaceutical Classification System (BCS) (WHO Technical Report Series No. 937, or later report)

☐ YES ☐ NO

If not (explain)

Reference product

Generic name	
Dosage form	
Dosage	
Trade name	
Manufacturer	
Manufacturing site	
Lot number	
Expiration date	

Name and address of the laboratory that carried out the tests:

Please attach the result of the in-vitro dissolution study report.
Study results

F2 (similarity factor) value (should be between 50-100%):

Value of F1 (difference factor):

Conclusions of the study:

4.2.3 By another method (please briefly describe the findings of the study)

Attach a graphical representation of the summary of the study results.

4.3 The product used in the therapeutic equivalence study is fundamentally the same as that which will be supplied (same materials from the same suppliers, same formula and same manufacturing method):

☐ YES ☐ NO

If no (explain what the differences are and justify why the differences do not impact bioavailability):

_____

_____

Provide a copy of the report of the proof of therapeutic equivalence (bioequivalence study) by comparison of the dissolution profile, dissolution tests, and other possible tests in Appendix AB.

For bioequivalence studies, indicate the inspection status by the relevant drug regulatory authority/WHO/Pharmaceutical Inspection Cooperation Scheme (PIC/S) of the Contract Research Organization (CRO) (if it has been subject to inspections in relation to the current study or other studies).

_____

_____

_____

_____

Attach a schematic representation of the study structure (Appendix AC)

Attach a summary of the study protocol (Appendix AD).

Section 5: Commitment and Authorization

5.1 Commitment

I, the undersigned, _____
(Function in the company, e.g. administrator, authorized person, Responsible Pharmacist), acting as manager in the company_____

(Company Name), certifies that the information given (above) is correct and true.

(If the product is marketed in the country of origin, check the appropriate box below)

☐ And that the product offered is identical in all respects to manufacturing and quality to the one that is marketed in _____

(Country of origin), including formulation, method and site of manufacture, sources of raw materials and excipients, quality control, packaging, shelf life and product information)

☐ And that the product offered is identical to that which is marketed in _____

(Name of country), except with respect to: _____

_____

_____

(e.g. formulation, method and site of manufacture, sources of raw materials and excipients, quality control, packaging, shelf life and product information)

If any changes occur to the product information after this questionnaire has been submitted, the manufacturer/supplier undertakes to provide the corresponding update as soon as possible.

Date: _____ Signature: _____

5.2 Power of Attorney

The manufacturer authorizes a distributor to submit the questionnaire

Date: _____ Signature: _____

Please provide a copy of the Power of Attorney (signed by the manufacturer's distributor under the Power of Attorney (Annex AE)

5.3 Authorization to share information with another organization

I, the undersigned, confirm that the company has no objection to the information contained herein being shared with the organizations listed on page 2 (1.5) with the exception of:

I, the undersigned, certify that the information provided above is accurate, correct, complete, current and true at the time of submitting the questionnaire.

Full name:

Full title/company function:

Company Name:

Date: _____ Signature: _____

Company stamp

Appendix No. 12: TECHNICAL SPECIFICATIONS OF MEDICAL CONSUMABLES

DESIGNATION	SPECIFICATIONS
WOODEN TONGUE DEPRESSOR -	Wooden tongue depressors must meet the following standards: ISO 13484, 14971, 10993, 22000, 21931, 11607, 14001, CEThey must have the following technical characteristics: - made of natural wood for its lightness, strength and hypoallergenic nature - rectangular, smooth, slightly rounded at the ends - designed to be single-use - dimensions: length: approximately 150mm width: approximately 18mm thickness: approximately 1.6mm
HAGE D'HORM 1/2 C CURVED NEEDLE ROUND POINT 40 mm - UNIT	Curved suture needles must be manufactured according to ISO 9626, 15223-1, CE standards. They must correspond to the following elements: - type of curve: 1/2 circle curve - total length of the needle: 40MM - diameter of the needle: 0.5MM - composition: surgical stainless steel - type of point: round point - compatibility: suitable for absorbable/non-absorbable suture thread
LUMBAR PUNCTURE NEEDLE 22GA-0.7x90MM -	Lumbar puncture needles must meet the following standards: ISO 13485, 9626, 7864, 80369-7, 11135, 11737-1, 11607-1, 11607-2, 10993-1, 10993-7, 15223-1, 20417, CE They must comply with the following characteristics: - surgical stainless steel needle, sterilized by gamma radiation or ethylene oxide - type: 22 Gauge (22G) - outer diameter: 0.7mm - total length: 90mm- precision sharpened tip, beveled, atraumatic tip (Quincke type)- plastic handle, black, non-toxic and sterilizable - Guide (inserted into the needle for better precision): Type: Flexible metal or plastic guide Role: To assist in the stabilization and correct positioning of the needle - individually packaged and single use

LUMBAR PUNCTURE NEEDLE 25G	Lumbar puncture needles must meet the following standards: ISO 13485, 9626, 7864, 80369-7, 11135, 11737-1, 11607-1, 11607-2, 10993-1, 10993-7, 15223-1, 20417, CE -surgical stainless steel needle, sterilized by gamma radiation or ethylene oxide Gauge: 25G (Gauge) – External diameter 0.5mm (approx). Length: Variable, usually between 90mm and 120mm. Material: High quality medical stainless steel, corrosion resistant. Hub Color (International Color Code 25G) Orange, facilitating identification of the caliber. Hub material: Transparent or opaque polypropylene - Guide (inserted into the needle for better precision): Type: Flexible metal or plastic guide Role: Assist in stabilization and correct positioning of the needle Sterile and single-use, avoiding any risk of cross-contamination.
EPICRANIAL NEEDLE 21G UU -	- The epicranial needles (micro perfusers) must meet the following standards: NFS 90 011, 90 013, 90 015, ISO 594-2, CE - They will have the following constituent elements: - a triple-bevel needle; - a needle protector; - two wings of standard green color for 21G micro perfusers Þ a transparent flexible PVC tube, 30cm long; Þ Each epicranial needle must be packaged in individual peelable blister packaging
EPICRANIAL NEEDLE 23G UU -	- The epicranial needles (micro perfusers) must meet the following standards: NFS 90 011, 90 013, 90 015, ISO 594-2, CE - They will have the following constituent elements: - a triple-bevel needle; - a needle protector; - two wings of standardized blue color for the 23G micro perfusers Þ a transparent flexible PVC tube, 30cm long; Þ Each epicranial needle must be packaged in individual peelable blister packaging.

EPICRANIAL NEEDLE 25G UU -	- The epicranial needles (micro perfusers) must meet the following standards: NFS 90 011, 90 013, 90 015, ISO 594-2, CE - They will have the following constituent elements: - a triple-bevel needle; - a needle protector; - two wings of standard orange color for 25G micro perfusers Þ a transparent flexible PVC tube, 30cm long; Þ Each epicranial needle must be packaged in individual peelable blister packaging
ELASTIC CREPE BAND 10 CM X 4M - UNIT	Crepe bandages must meet the standards ISO 13485, 10993, CEThey must comply with the following characteristics:- main composition: 80-100% cotton - integrated stretch fibers for elasticity.- soft and slightly rough surface.- elastic elongation up to 100-120% - packaging: individual roll packed in a sterile bag. - dimensions: width: 10CMlength: 4M
HYDROPHILIC GAUZE STRIP 17 THREADS - 90CMX91M - UNIT-	Gauze bandages must meet ISO 13485standards, CEThey must comply with the following characteristics:- type: woven in hydrophilic gauze- density: 17 threads/m2 (standard mesh for medical use)- structure: square mesh with good spacing.- composition: 100% pure hydrophilic cotton- absorption: high liquid absorption capacity, suitable for cleaning and application of disinfectant solutions.- packaging: 91M roll/sheet of gauze, wrapped in non-sterile paper- dimensions: width: 90CMlength: 91M

NON-STERILE GAUZE BAND 10CMX4M - UNIT -	Non-sterile gauze bandages must meet the standards ISO 13485, 10993-1, 20645, 2859, CEThey must correspond to the following elements: - dimensions and format: width: 10CM length: 4M thickness: 0.5MM - composition: 100% hydrophilic cotton - structure: loose knit fabric - absorption: high liquid absorption capacity - finishing: unhemmed edges, straight cut - non-sterile
NON-STERILE GAUZE STRIP 5CMX4M - UNIT -	Non-sterile gauze bandages must meet the standards ISO 13485, 10993-1, 20645, 2859, CEThey must correspond to the following elements: - dimensions and format: width: 5CM length: 4M thickness: 0.5MM - composition: 100% hydrophilic cotton - structure: loose knit fabric - absorption: high liquid absorption capacity - finishing: unhemmed edges, straight cut - non-sterile
PLASTER BAND 3M x 10CM - UNIT	Plaster bandages must be manufactured according to the standards ISO 15609, 4074, 22312, 11607, ISO 15223-1, 9001, 20417, 14001, 18113, CE. They must comply with the following characteristics: - dimensions: length: 3M width: 10CM Support: Cotton gauze or synthetic fiber, light and flexible Coating: Quick-setting plaster

REEL OF ABSORBABLE THREAD (POLYGLA) 3/0 (dec 2) WITHOUT NEEDLE 250CM - UNIT	Absorbable sutures must meet the standards: ISO 13485, CE They must correspond to the following characteristics: - thread material: polyglactin 910 - type: absorbable - thread gauge: USP 3/0, metric decimal 2 - thread length: 250 CM - thread color: purple - packaging: without needle - sterilization: by ethylene oxide or gamma rays - unit: packaged in a reel, with a tear-off aluminum foil pouch and a sterile sachet
REEL OF ABSORBABLE THREAD (POLYGLACTIN 2/0 (dec3) without needle 250cm - UNIT	Absorbable sutures must meet the standards: ISO 13485, CE They must correspond to the following characteristics: - thread material: polyglactin 910 - type: absorbable - thread gauge: USP 2/0, metric decimal 3 - thread length: 250 CM - thread color: purple - packaging: without needle - sterilization: by ethylene oxide or gamma rays - unit: packaged in a reel, with a tear-off aluminum foil pouch and a sterile sachet
RESORBABLE THREAD REEL (POLYGLACTIN 1 dec4 SS AIG 250CM-VICRYL- UNIT	Absorbable sutures must meet the standards: ISO 13485, CE They must correspond to the following characteristics: - thread material: polyglactin 910 - type: absorbable - thread gauge: USP 1/0, metric decimal 4 - thread length: 250 CM - thread color: purple - packaging: without needle - sterilization: by ethylene oxide or gamma rays - unit: packaged in a reel, with a tear-off aluminum foil pouch and a sterile sachet

GUEDEL CANNULA SIZE 1 - PVC - UNIT	Guedel cannulas must be manufactured according to ISO 13485, 10993, 11135, 11137, 15001, CE They must meet the following characteristics: - material: high quality, flexible and robust PVC (polyvinyl chloride) - outer lining: made of polyethylene - sterility: product sterilized by ethylene oxide or radiation - size: 1 - dimensions: length: 7 CM - color: white - shape: curved
GUEDEL CANNULA SIZE 2 - PVC - UNIT	Guedel cannulas must be manufactured according to ISO 13485, 10993, 11135, 11137, 15001, CE standards. They must meet the following characteristics: - material: high quality, flexible and robust PVC (polyvinyl chloride) - outer lining: made of polyethylene - sterility: product sterilized by ethylene oxide or radiation - size: 2 - dimensions: length: 8 CM - color: green - shape: curved
GUEDEL CANNULA SIZE 3 - PVC - UNIT	Guedel cannulas must be manufactured according to ISO 13485, 10993, 11135, 11137, 15001, CE standards. They must meet the following characteristics: - material: high quality, flexible and robust PVC (polyvinyl chloride) - outer lining: made of polyethylene - sterility: product sterilized by ethylene oxide or radiation - size: 3 - dimensions: length: 9 CM - color: green - shape: curved

SHORT CATHETER - G14 - UU STE - UNIT -	Catheters must meet AFNOR NF S 90-040 standards. Catheters must have: Þ a silicone needle, tapered with triple bevel with orientation lug ensuring easier and less traumatic penetration; Þ flexible wings ensuring safe and comfortable fixation Þ a transparent reflux chamber with hydrophobic membrane obturator and universal obturator. Þ An injection site Dimensions and Identification Gauge: 14 Gauge (14G) External diameter: approximately 2.1 mm Length: generally 45 mm Color code: orange, according to ISO 10555-5
SHORT CATHETER - G18 - UU STE - UNIT -	Catheters must meet AFNOR NF S 90-040 standards. Catheters must have: a silicone needle, tapered with triple bevel with orientation lug ensuring easier and less traumatic penetration; flexible wings ensuring safe and comfortable fixation; a transparent reflux chamber with hydrophobic membrane obturator and universal obturator. Þ An injection siteDimensions and IdentificationGauge: 18 Gauge (18G)Outer diameter: approximately 1.3 mmLength: typically 32 or 45 mmColor code: green, according to ISO 10555-5
SHORT CATHETER - G20- UU STE - UNIT -	Catheters must meet AFNOR NF S 90-040 standards. Catheters must have: Þ a silicone needle, tapered with triple bevel with orientation lug ensuring easier and less traumatic penetration; Þ flexible wings ensuring safe and comfortable fixation Þ a transparent reflux chamber with hydrophobic membrane obturator and universal obturator. Þ An injection site Dimensions and Identification Gauge: 20 Gauge (20G) External diameter: approximately 1.3 mm Length: generally 32 or 45 mm Color code: green, according to ISO 10555-5

SHORT CATHETER - G22 - UU STE - UNIT -	Catheters must meet AFNOR NF S 90-040 standards. Catheters must have: Þ a silicone needle, tapered with triple bevel with orientation lug ensuring easier and less traumatic penetration; Þ flexible wings ensuring safe and comfortable fixation Þ a transparent reflux chamber with hydrophobic membrane obturator and universal obturator. Þ An injection site Dimensions and Identification Gauge: 22 Gauge (22G) External diameter: approximately 0.9 mm Length: generally 19 mm - 25 mm Color code: blue, according to ISO 10555-5
SHORT CATHETER - G24 - UU STE - UNIT -	Catheters must meet AFNOR NF S 90-040 standards. Catheters must have:Þ a silicone needle, tapered with triple bevel with orientation lug ensuring easier and less traumatic penetration;Þ flexible wings ensuring safe and comfortable fixationÞ a transparent reflux chamber with hydrophobic membrane obturator and universal obturator.Þ An injection siteDimensions and IdentificationGauge: 24 Gauge (24G)External diameter: approximately 0.7 mmLength: generally 19 mmColor code: yellow, according to ISO 10555-5
UU BAR UMBILICAL CLAMP - UNIT -	Dimensions: - total length: 5.5MM - width: 10MM - jaw thickness: 3MM- closure type: secure locking mechanism (self-locking), "UU bar" type- jaw shape: serrated- clamping force: tested to ensure secure closure and prevent blood leakage- opening and closing: easy to handle with one hand- packaging: sterile, individual

HYDROPHILIC COMPRESS 10CMX10CM NON-WOVEN -	Sterile non-woven hydrophilic compresses must be made of purified cellulose, Dimension 10 cm x 10 cm, folded format, weighing 40g/m2, and 4 thicknesses. Their absorption capacity must be 10g/l. The breaking strength must be on average 35 N/5cm and 14 N/5cm across. They must not fray. They must have a bacterial contamination of less than 100 cfu/g.
STERILE COMPRESS 40 X40 (10cm x 10cm FOLDED) -	Dimensions: Unfolded: 40 x 40 cm Folded: 10 x 10 cm (for easy packaging and use) Shape: Folded into a compact size for easy use while providing a large surface area when unfolded. Fabric Type: Woven cotton or woven polyester, ensuring high strength and excellent absorbency Woven to prevent easy tearing while maintaining the flexibility needed for easy handling Each compress is individually wrapped in a sealed bag Convenient packaging, allowing the compress to be easily removed without compromising sterility
HYDROPHILIC COTTON 500G - PACKAGE-	Material: 100% pure cotton, natural fibersWeight: 500 gTexture: non-irritating to the skinAbsorption: High capacity for absorbing liquids (disinfectants, antiseptics, exudates)Presentation: Packaged in a hermetic package to guarantee hygieneEasy to cut and handle
HYDROPHILIC COTTON 50G - PACKAGE-	Material: 100% pure cotton, natural fibersWeight: 50 gTexture: non-irritating to the skinAbsorption: High capacity for absorbing liquids (disinfectants, antiseptics, exudates)Presentation: Packaged in a hermetic package to guarantee hygieneEasy to cut and handle

CH16 REDON DRAIN - UNIT	Type: Redon drain (closed circuit suction drain)Caliber (Charrière, CH): 16 CHExternal diameter: ≈ 5.3 mmLength: 50 cm to 100 cmMaterial: Silicone or soft medical PVC Distal end: Perforated over several centimeters Proximal end: Connectable to a vacuum collection systemUse: Single use (sterile)
CH8 REDON DRAIN - UNIT	Type: Redon drain (suction, closed circuit)Caliber (Charrière, CH): 8 CHExternal diameter: ≈ 2.67 mmLength: 30 cm to 50 cmMaterial: Medical silicone or soft PVC (sterile, single use)Distal end: Perforated over several centimetersProximal end: Connectable to a vacuum collection systemUse: Single use (sterile)
CH28 THORACIC DRAIN - UNIT WITH CHUCK	Type: Redon drain with introducer mandrel (closed circuit suction drain)Caliber (Charrière, CH): 28 CHExternal diameter: ≈ 9.3 mmLength: 50 cm to 100 cm (varies depending on the model)Material: Medical silicone or soft PVCMandrel: Rigid, facilitates the introduction of the drainDistal end: Perforated over several centimetersProximal end: Connectable to a vacuum drainage systemDrainage mode: Passive or active suction (with vacuum bottle)

SKIN WIRE 3/0 CRIMPED - UNIT	Type: Non-absorbable sutureGauge: 3/0 (approximately 0.2 mm diameter according to USP standards)Material: Polyamide (nylon) Texture: Monofilament (reduces the risk of infection and ensures better glide) Thread length: 90cm2. Crimped needleType: Curved needle 1/2 circleNeedle length: 30 mmPoint: Triangular or sharp (ideal for skin and dense tissues)
NON-RESORBED WIRE (Polyest.) Braided 2/0 (Dec.3) CRIMPED AIG1/2C.-26mm-UNIT	Type: Non-absorbable suture threadGauge: 2/0 (Dec. 3), i.e. a diameter of 0.2 - 0.3 mmMaterial: Braided polyester (soft, high strength, good knot retention)Structure: Braided for better handling and good knot retentionThread length: 90cmNeedle: Type: 1/2 circle (curvature facilitating the suturing of deep tissues)Length: 26 mmPoint: Round (atraumatic) for soft and fragile tissues
NON-RESORBABLE NYLON THREAD (POLYAMIDE) 2/0 (dec3) AIG 3/8C 90CM – UNIT	Type: Non-absorbable suture threadGauge: 2/0 (Dec. 3) – diameter ≈ 0.2 - 0.3 mm Material: Polyamide (nylon)Structure: Monofilament (smooth, reduces risk of infection)Thread length: 90 cmNeedle:Type: 3/8 circle Length: 25 mmPoint: Sharp (triangular) for tough fabrics

POLYGLACTIN FAST WIRE 2/0 dec3 AIG 1/2C ARR - UNIT	Type: Rapid absorbable sutureGauge: 2/0 (Dec. 3) – diameter ≈ 0.2 - 0.3 mm Material: Polyglactin 910Structure: Braided and coated5748Thread length: 75 cmNeedle:Type: 1/2 circle Length: 26 mmPoint: Atraumatic (round), designed to minimize tissue damage
RESORBABLE THREAD (POLYGLACTIN) 3/0 (dec2) AIG.1/2C.75CM – UNIT	Type: Rapid absorbable sutureMaterial: Polyglactin 910Gauge: 2/0 (Dec. 3) – diameter ≈ 0.2 - 0.3 mmStructure: Braided and coatedThread length: 70 - 75 cmNeedle:Type: 1/2 circle atraumatic (allows gentle penetration of tissues)Length: Typically 19 mm to 30 mmPoint:Sharp (triangular) for tough tissues (skin, fascia)Atraumatic (round) for fragile tissues
RESORBABLE POLYGLACTIN THREAD 1dec4 AIG 1/2C ARR-75CM- UNIT	Type: Absorbable sutureMaterial: Polyglactin 910Gauge: 1 dec. 4 (equivalent to a diameter of ≈ 0.4 mm)Structure: Braided (for good tensile strength and easy handling)Thread length: 75 cmNeedle:Type: 1/2 circle atraumatic (for smooth and gentle penetration of tissue)Needle length: Typically 19 mm to 30 mmPoint: Atraumatic (round), suitable for gentle manipulation of soft tissues

RESORBABLE POLYGLACTIN THREAD 1dec4 AIG 3/8C ARR-70CM- UNIT	Thread Type: AbsorbableMaterial: Polyglactin 910Thread Gauge: 1 Dec. 4 (approximately 0.4 mm in diameter)Construction: Braided (providing good strength and easy handling, with strong knot holding)Thread Length: 70 cmNeedle:Needle Type: 3/8 circlePoint: Atraumatic, designed to minimize tissue damage during suturing.Needle Length: Typically 19 mm to 30 mm
RESORBABLE POLYGLACTIN THREAD 2/0 dec3 AIG 1/2C ARR-UNIT	Thread Type: AbsorbableMaterial: Polyglactin 910Thread Gauge: 2/0 (Dec. 3) (approximately 0.3 mm in diameter)Construction: Braided and coated for increased tensile strength and knot retentionThread Length: Typically 75 cm to 90 cmNeedle:Needle Type: Atraumatic 1/2 circle (provides smooth and precise tissue penetration)Needle Length: Typically 19 mm to 30 mmPoint: Atraumatic (round), designed to minimize tissue damage during suturing
LATEX SURGICAL GLOVES UU N°7 - PAIR -	Sterile single-use surgical gloves must meet the following requirements: - made of natural latex, internally powdered with FDA-approved corn starch, - anatomically shaped with right and left hand indication in double packaging, - with a cuff with a wrist reinforced by a rolled edge, hypoallergenic. Size 7 surgical gloves must have the following dimensions: length of at least 270 mm, width at the palm of 89 mm +/- 5 mm. The double packaging must be easily peelable (with sagittal opening), to avoid asepsis errors as much as possible. Packaging that can be cut with scissors is not accepted. Single-use sterile surgical gloves will be packaged in pairs.

LATEX SURGICAL GLOVES UU N°7 1/2 - PAIR –	Sterile single-use surgical gloves must meet the following requirements: - made of natural latex, internally powdered with FDA-approved corn starch, - anatomically shaped with right and left hand indication in double packaging, - with a cuff with a wrist reinforced by a rolled edge, hypoallergenic. Size 7 surgical gloves must have the following dimensions: length of at least 270 mm, width at the palm of 95 mm +/- 5 mm. The double packaging must be easily peelable (with sagittal opening), to avoid asepsis errors as much as possible. Packaging that can be cut with scissors is not accepted. Single-use sterile surgical gloves will be packaged in pairs.
NON-STERILE LATEX EXAMINATION GLOVES. SIZE LARGE -	Non-sterile examination gloves must meet the AFNOR NFS 90 001 or ISOÞ standards Conformity of non-sterile latex examination gloves, size large (8.5/9)Non-sterile latex gloves must have the following characteristics: made of natural latex, with an internal powdering of resorbable organic corn starch. They must be ambidextrous, with a reinforced wrist with a rolled edge, and hypoallergenic. The required dimensions are as follows: large size (8.5/9), with a minimum length of 240 mm to 250 mm
NON-STERILE LATEX EXAMINATION GLOVES. MEDIUM SIZE -	Non-sterile examination gloves must meet the AFNOR NFS 90 001 or ISOÞ standards Compliance of non-sterile latex examination gloves, medium size (7/8)Non-sterile latex gloves must have the following characteristics: made of natural latex, with an internal powdering of resorbable organic corn starch. They must be ambidextrous, and have a reinforced wrist with a rolled edge, and hypoallergenic. The required dimensions are as follows: medium size (7/8), with a minimum length of 230 mm
POWDERED LATEX EXAMINATION GLOVES SIZE SMALL -	Non-sterile size 6/7 latex examination gloves must have the following characteristics: made of natural latex, with an internal coating of resorbable organic corn starch. They must be ambidextrous, with a reinforced wrist with a rolled edge, and hypoallergenic. The required dimensions are as follows: small size (6/7), with a minimum length of 230 mm
GYNECO STER GLOVES. LONG SLEEVE - MEDIUM SIZE - PAIR -	Type: Sterile Gynecological GlovesMaterial: Natural LatexSize: Medium (usually for hands with a palm width of about 8-8.5cm)Total Length: Long sleeve, usually 30-35cm, for full coverage of hands and forearmsThickness: Approximately 0.12-0.15mm, providing a balance of strength and tactile sensitivityCuff: Rolled to ensure a good seal and fixation at the base of the armFit: Ambidextrous, for easy use on both left and right handsSterility: Sterile, pre-packed in individual sachets to ensure sterility

SAMPLING TOURNIQUET - UNIT	Material: Rubber, latex or polyurethane (depending on the model) Hypoallergenic (latex-free for some models) to avoid allergic reactions Type: Single-use sampling tourniquet Length: Approximately 40 to 45 cm, to accommodate various arm sizes Width: Typically 1.5 to 2 cm Elasticity: Designed to have enough tension to be effective while remaining comfortable
TUBULAR JERSEY 10 CMx25M- UNIT -	Dimensions: Width: 10 cm (suitable for areas such as arms, wrists, ankles, etc.) Length: 25 meters (providing sufficient length for extended use and adaptable to various applications) Material: Elastic knitted textile of cotton, polyester, or a combination of both, allowing good elasticity and optimal comfort Stretchable material to adapt to different body sizes and shapes Finish: Tubular knit, which means that it is formed in the form of a tube, without seams, to ensure a comfortable and irritation-free fit Properties: Elasticity and flexibility to adapt to different areas of the body
SURGERY SCALP BLADE N°11 UU -	Scalpel blades must meet BS 2982 or ISO 7740 standards. They must be made of stainless steel, gamma sterilized, and packaged in individual peelable packaging. The size and legal notices must be clearly legible and identifiable on the primary packaging. Carbon blades are not accepted. Dimensions: Total length: Approx. 22 to 24 mm Width: Approx. 6mm Thickness: About 0.3 mm
SURGERY SCALP BLADE N°15 UU -	Scalpel blades must meet BS 2982 or ISO 7740 standards. They must be made of stainless steel, gamma sterilized, and packaged in individual peelable packaging. The size and legal notices must be clearly legible and identifiable on the primary packaging. Carbon blades are not accepted. Dimensions: Total length: Approx. 19mm to 21mm Width: Approx. 4mm Thickness: About 0.3mm to 0.4mm
SURGERY SCALP BLADE N°21 UU -	Scalpel blades must meet BS 2982 or ISO 7740 standards. They must be made of stainless steel, gamma sterilized, and packaged in individual peelable packaging. The size and legal notices must be clearly legible and identifiable on the primary packaging. Carbon blades are not accepted. Dimensions: Total length: Approx. 32mm to 34mm Width: Approx. 7mm

	Thickness: About 0.5mm to 0.6mm
SURGERY SCALP BLADE N°24 UU -	Scalpel blades must meet BS 2982 or ISO 7740 standards. They must be made of stainless steel, gamma sterilized, and packaged in individual peelable packaging. The size and legal notices must be clearly legible and identifiable on the primary packaging. Carbon blades are not accepted. Dimensions: Total length: Approx. 39mm to 42mm Width: Approx. 10 mm Thickness: About 0.5mm to 0.6mm
ADULT OXYGEN GLASSES - UNIT	Type: Adult Oxygen GogglesMaterial: PVC (polyvinyl chloride), silicone, or other soft and durable material Hypoallergenic to minimize the risk of allergies or skin irritationLength: Approximately 1.8 to 2.1 meters, adjustable to adapt to the patient's morphology and allow freedom of movementDesign: Soft and flexible tubes allowing a comfortable fit on the patient's faceErgonomic nasal tips adapted to the size of the nostrils, providing good fixation without being uncomfortableLength of the nostril tips: 13mm Diameter of the nostril tips: 5.8mmFlow rate: Compatible with oxygen flow rates ranging from 6 L / min, according to the medical prescriptionAllows a continuous and moderate supply of oxygen, providing optimal comfort to the patient

PEDIATRIC OXYGEN GLASSES - UNIT	Type: Children's Oxygen GogglesMaterial: PVC (polyvinyl chloride), silicone, or other soft and durable material, ensuring patient comfort and avoiding irritationHypoallergenic to minimize the risk of allergies or skin irritationLength: Approximately 1.8 to 2.1 meters, adjustable to adapt to the patient's morphology and allow freedom of movementDesign: Soft and flexible tubes allowing a comfortable fit on the patient's faceErgonomic nasal tips adapted to the size of the nostrils, providing good fixation without being uncomfortableFlow rate: Compatible with oxygen flow rates ranging from 1 to 4 L / min, according to the medical prescriptionAllows a continuous and moderate supply of oxygen, providing optimal comfort to the patient
OXYGEN GLASSES FOR NEWBORN	Type: Newborn Oxygen GoggleMaterial: PVC (polyvinyl chloride), silicone, or other soft and durable material, ensuring patient comfort and avoiding irritationHypoallergenic to minimize the risk of allergies or skin irritationLength: Approximately 1.8 to 2.1 meters, adjustable to fit the patient's morphology and allow freedom of movementDesign: Soft and flexible tubes allowing a comfortable fit on the patient's faceErgonomic nasal tips adapted to the size of the nostrils, providing good fixation without being uncomfortableFlow rate: Compatible with oxygen flow rates ranging from 1.5 to 2 L / min, according to the medical prescriptionAllows a continuous and moderate supply of oxygen, providing optimal comfort to the patient

STANDARD PET OXYGEN MASK - UNIT	Type: Standard Oxygen MaskMaterial: Clear, soft and lightweight medical PET (Polyethylene Terephthalate)Size: Ergonomically shaped for an optimal fit on the faceFixation: Adjustable elastic strap to ensure a secure and comfortable fitAdjustable metal or plastic nose clip to prevent oxygen leakageConnection: Standard oxygen tube with universal mouthpiece compatible with sources Tube length: approximately 2 meters to ensure freedom of movement for the patientOxygen flow rate: Suitable for a flow rate of 5 to 15 L/min, depending on the patient's needsEnsures a FiO_2(fraction inspired in oxygen) from 40 to 60%, variable according to the flow rate and the adjustment of the maskExpiration valve: Some models may include side openings allowing the evacuation of CO_2
SYNTHETIC WADDING (carded cotton) 2.7M x 7.5CM - UNIT	Type: Synthetic wadding (carded cotton)Dimensions: 2.7 meters length x 7.5 cm widthMaterial: Non-woven synthetic fibers or carded cotton Hypoallergenic, preventing skin irritationGood air permeability, allowing the skin to breatheResistant to tension and tears, ensuring good hold under a bandage or castAbsorption: Moderate absorption capacity, helping to manage moisture without compromising the fixation of the bandage
STERILE "Y" INFUSER - UNIT	Components: *Tubing: Typically, a main tube (usually made of soft PVC) that splits into two Y-shaped branches to allow the independent but controlled administration of fluids or medications Internal Diameter (lumen): Varies, often 1.0mm to 4.0mm depending on type and application Total length: Approximately 150 cm to 200 cm, depending on clinical needs *Connectors: Luer-lock or luer-slip connectors to ensure a secure connection with needles, syringes or other medical devices Some versions include built-in filters or security keys to prevent errors in administration *Accessories : Stoppers or valve systems to isolate each branch, allowing each solution to be infused independently Flow Adjustment: Some versions include a built-in flow regulator or manual control to adjust the flow of each infusion Anti-clog and anti-reflux devices to ensure proper flow without cross-contamination *Material : Tubing made of medical PVC or polyethylene, transparent material allowing visualization of the liquid flow and resistant to bending and twisting

2L URINE COLLECTION BAG WITH DRAIN - UNIT -	It must meet the ISO or NFS 90-631 standards. The urine collection bag must have the following characteristics: transparent PVC with a white background, graduated in 100 ml, with a nominal volume of 2 liters, with a non-return valve and a push-pull drain tap. It is equipped with 2 reinforced suspension holes, a translucent tube 90 cm long, with an internal diameter of 5 mm, a notched connector with cap, conical, standardized, adaptable to all bladder catheters and penile sheaths.
3-WAY FITTING – UNIT	Material: Clear medical grade polycarbonate (impact and chemical resistant) Sterile and non-pyrogenic Connection: Universal inlet and outlet (compatible with standard Luer-Lock and Luer-Slip devices) Can be connected to syringes, catheters, IV tubing, etc. Rotation: 360° rotating stopcock for easy orientation and flow adjustment Secure locking system to prevent leaks and administration errors Maximum pressure supported: Approximately 4.5 bar (65 psi) Usage: Single use (disposable device)
FEEDING SYRINGE 50ML/60ML UU - UNIT	Medical device used for the enteral administration of nutrient or medicinal liquids to patients unable to eat normally orally. It is specially designed to be used with feeding or feeding tubes.Material:Transparent medical polypropylene (allowing good visibility of the liquid)Latex-free (reduces the risk of allergy)Sterile and non-pyrogenic (ensuring maximum safety for the patient)Graduation:Readable and precise graduations in mL for exact dosageIndelible for better durabilityTip:Catheter tip (ENFit or Luer type), specially designed for connection to feeding tubesPrevents connection errors with intravenous devicesPiston:Smooth and precise movement for controlled administrationMedical rubber seal ensuring a perfect sealUse:Single use (prevents cross-contamination)Suitable for enteral feeding and the administration of thick liquids

HYPODERMIC SYRINGE LUER 10ML UU WITH NEEDLE 21G -	Capacity: 10 mLConnection Type: Luer Lock TipMaterial: Clear medical polypropylene barrelLatex-free medical rubber seal (hypoallergenic)Sterile and non-pyrogenicGraduations: Readable and indelible (in mL)High precision for exact dosingPiston: Smooth and precise glideSafety stop prevents accidental withdrawal of the pistonNeedle: Gauge (G): 21G (0.8 mm diameter)Length: 25 to 40 mm depending on the modelMaterial: Durable and biocompatible medical stainless steelTriple-sharpened bevel for atraumatic penetrationFixation: Luer Lock compatibleSecure connection reduces the risk of leakage

HYPODERMIC SYRINGE LUER 20ML UU WITH NEEDLE 21G -	Capacity: 20 mLConnection Type: Luer Lock TipMaterial: Clear medical polypropylene barrelLatex-free medical rubber seal (hypoallergenic)Sterile and non-pyrogenicGraduations: Readable and indelible (in mL)High precision for exact dosingPiston: Smooth and precise glideSafety stop prevents accidental withdrawal of the pistonNeedle: Gauge (G): 21G (0.8 mm diameter)Length: 25 to 40 mm depending on the modelMaterial: Durable and biocompatible medical stainless steelTriple-sharpened bevel for atraumatic penetrationFitting: Luer Lock compatibleSecure connection reduces the risk of leakage

HYPODERMIC SYRINGE LUER 2ML UU WITH NEEDLE 23G -	Capacity: 2 mLConnection Type: Luer Lock TipMaterial: Clear medical polypropylene barrelLatex-free medical rubber seal (hypoallergenic)Sterile and non-pyrogenicGraduations: Clear and indelible (in mL)High precision for exact dosingPiston: Smooth and precise glideSafety stop prevents accidental withdrawal of the pistonNeedle: Gauge (G): 23G (0.6 mm diameter)Length: 25 mm to 32 mm, depending on the modelMaterial: High quality medical stainless steelTriple-ground bevel for atraumatic penetrationAttachment: Luer Lock compatibleSecure connection reduces the risk of leakage

HYPODERMIC SYRINGE LUER 5ML UU WITH 21G NEEDLE -	Capacity: 5 mLConnection Type: Luer Lock TipMaterial: Clear medical polypropylene barrelLatex-free medical rubber seal (hypoallergenic)Sterile and non-pyrogenicGraduations: Readable and indelible (in mL)High precision for exact dosingPiston: Smooth and precise glideSafety stop prevents accidental withdrawal of the pistonNeedle: Gauge (G): 21G (0.8 mm diameter)Length: 25 to 40 mm depending on the modelMaterial: Durable and biocompatible medical stainless steelTriple-sharpened bevel for atraumatic penetrationFixation: Luer Lock compatibleSecure connection reduces the risk of leakage
INSULIN SYRINGE 100U 1ML UU WITH NEEDLE 29G -	1. SyringeCapacity: 1 mL (graduated in 100 units of insulin)Tip Type: Integrated needle (prevents insulin loss and reduces dead space)Material: Transparent, durable and non-toxic medical polypropylene bodyLatex-free medical rubber plunger (hypoallergenic)Accurate graduations: Marked in units (100U/ml) for exact dosingIndelible and contrasting inks for easy readingSafety stop: Prevents accidental overflow of the plunger2. NeedleGauge (G): 29G (0.33 mm diameter)Length: 12.7 mm or 8 mm (depending on the model)Material: Surgical stainless steel, ultra-fine and durableSharpness: Triple bevel for easy and atraumatic penetrationLubrication: Reduces pain during injection

HYPODERMIC SYRINGE LUER 50ML UU WITH AIG -	Capacity: 50 mLConnection Type: Luer Lock TipMaterial: Clear medical polypropylene barrelLatex-free medical rubber seal (hypoallergenic)Sterile and non-pyrogenicGraduations: Readable and indelible (in mL)High precision for exact dosingPiston: Smooth and precise glideSafety stop prevents accidental withdrawal of the pistonNeedle: Gauge (G): 21G (0.8 mm diameter)Length: 25 to 40 mm depending on the modelMaterial: Durable and biocompatible medical stainless steelTriple-sharpened bevel for atraumatic penetrationFixation: Luer Lock compatibleSecure connection reduces the risk of leakage
DUODENAL SUCTION PROBE LEVIN CH12-125CM - UNIT -	Type: Levin type nasogastric/duodenal tubeDiameter: CH12 (approx. 4 mm)Length: 125 cmOpen distal end, 4 side ports, centimeter marking from 5 to 75 cmMaterial: Soft and biocompatible medical PVC with ORX linePhthalate and latex free (hypoallergenic)Transparent for better visualization of secretions
PVC BRONCHIAL SUCTION PROBE CH10 UU - UNIT	Bronchial suction probes (De Lee type) must be made of PVC, open end, straight and blunt, 2 side holes, 40 to 50 cm longDiameter: CH10 (≈ 3.3 mm internal diameter)
PVC BRONCHIAL SUCTION PROBE CH18 UU - UNIT	Bronchial suction probes (De Lee type) must be made of PVC, open end, straight and blunt, 2 side holes, 40 to 50 cm longDiameter: CH18 (≈ 6 mm internal diameter)

PVC BRONCHIAL SUCTION PROBE CH5 UU - UNIT	Bronchial suction probes (De Lee type) must be made of PVC, open, straight and blunt end, 2 side holes, 30 to 50 cm longDiameter: CH5 (≈ 1.67 mm internal diameter)
PVC BRONCHIAL SUCTION PROBE CH6 UU - UNIT	Bronchial suction probes (De Lee type) must be made of PVC, open end, straight and blunt, 2 side holes, 30 to 50 cm longDiameter: CH6 (≈ 2.0 mm internal diameter)
PVC BRONCHIAL SUCTION PROBE CH8 UU - UNIT	Bronchial suction probes (De Lee type) must be made of PVC, open, straight and blunt end, a side orifice, 30 to 50 cm longDiameter: CH8 (≈ 2.7 mm internal diameter)
TRACHEAL SUCTION TUBE WITH CH14 UU CONTROL VALVE - UNIT	Type: Soft tracheal suction tube with control valve Open, straight and blunt end, 2 side ports Diameter: CH14 (≈ 4.7 mm internal diameter) Length: 40 to 50 cm Material: Soft and transparent medical PVC, facilitating the visualization of the device and secretions Phthalate and latex free, to reduce the risk of allergies and irritation Biocompatible and non-toxic
TRACHEAL SUCTION TUBE WITH CH6 UU CONTROL VALVE - UNIT	Type: Soft tracheal suction tube with check valve Open, straight, blunt tip, 2 side ports Diameter: CH6 (≈ 2.0 mm internal diameter) Length: 30 to 40 cm Material: Soft, transparent medical PVC, facilitating visualization of the device and secretions Phthalate and latex free, to reduce the risk of allergies and irritation Biocompatible and non-toxic
CH14 UU PVC TRACHEAL SUCTION TUBE - UNIT	Type: Soft tracheal suction tubeOpen, straight and blunt end, 2 side portsDiameter: CH14 (≈ 4.7 mm internal diameter)Length: 40 to 50 cmMaterial: Soft and transparent medical PVC, facilitating the visualization of the device and secretionsPhthalate and latex free, to reduce the risk of allergies and irritationBiocompatible and non-toxic

ENDOTRACHEAL TUBE WITH PVC CUFFS 6.0mm - UNIT	1. TubeType: Endotracheal tube with cuffInner diameter: 6.0 mm (about 6 mm inner diameter)Outer diameter: About 8.0 mmLength: 20 to 30 cmMaterial: Soft and transparent medical PVC, allowing clear observation of secretions and the tube2. CuffCuff type: Pressure-controlled cuff to ensure optimal airway sealing and prevent leakage during ventilationCuff material: Soft and smooth PVC, ensuring low friction to minimize the risk of tracheal irritationCuff volume: Pre-filled or can be inflated to a specific pressure according to the patient's needsShape: Adapted to the human trachea to ensure effective sealing and prevent accumulation of secretions3. Proximal ConnectionProximal Tip: Standard Luer-type connection for compatibility with balloon inflation syringe and ventilation devicesPossibility to connect a pressure monitoring device to monitor balloon inflationGraduations: Graduations on the tube for precise positioning during intubation4. Sterilization and SafetyIndividually sterile packagingSingle use, reducing the risk of cross-infection and contamination

ENDOTRACHEAL TUBE WITH PVC BALLOON 6.5mm - UNIT	1. TubeType: Endotracheal tube with cuffInner diameter: 6.5mm (about 6.5mm inner diameter)Outer diameter: About 8.5mmLength: 20-30cmMaterial: Soft and transparent medical PVC, allowing clear observation of secretions and the tube2. CuffCuff type: Pressure-controlled cuff to ensure optimal airway sealing and prevent leakage during ventilationCuff material: Soft and smooth PVC, ensuring low friction to minimize the risk of tracheal irritationCuff volume: Pre-filled or can be inflated to a specific pressure according to the patient's needsShape: Adapted to the human trachea to ensure effective sealing and prevent accumulation of secretions3. Proximal ConnectionProximal Tip: Standard Luer-type connection for compatibility with balloon inflation syringe and ventilation devicesPossibility to connect a pressure monitoring device to monitor balloon inflationGraduations: Graduations on the tube for precise positioning during intubation4. Sterilization and SafetyIndividually sterile packagingSingle use, reducing the risk of cross-infection and contamination

ENDOTRACHEAL TUBE WITH PVC CUFFS 7.0mm - UNIT	1. TubeType: Endotracheal tube with cuffInner diameter: 7.0 mm (about 7.0 mm inner diameter)Outer diameter: About 9.0 mmLength: 20 to 30 cmMaterial: Soft and transparent medical PVC, allowing clear observation of secretions and the tube2. CuffCuff type: Pressure-controlled cuff to ensure optimal airway sealing and prevent leakage during ventilationCuff material: Soft and smooth PVC, ensuring low friction to minimize the risk of tracheal irritationCuff volume: Pre-filled or can be inflated to a specific pressure according to the patient's needsShape: Adapted to the human trachea to ensure effective sealing and prevent accumulation of secretions3. Proximal ConnectionProximal Tip: Standard Luer-type connection for compatibility with balloon inflation syringe and ventilation devicesPossibility to connect a pressure monitoring device to monitor balloon inflationGraduations: Graduations on the tube for precise positioning during intubation4. Sterilization and SafetyIndividually sterile packagingSingle use, reducing the risk of cross-infection and contamination

ENDOTRACHEAL TUBE WITH PVC BALLOON 7.5mm - UNIT	1. TubeType: Endotracheal tube with cuffInner diameter: 7.0 mm (about 7.0 mm inner diameter)Outer diameter: About 9.0 mmLength: 20 to 30 cmMaterial: Soft and transparent medical PVC, allowing clear observation of secretions and the tube2. CuffCuff type: Pressure-controlled cuff to ensure optimal airway sealing and prevent leakage during ventilationCuff material: Soft and smooth PVC, ensuring low friction to minimize the risk of tracheal irritationCuff volume: Pre-filled or can be inflated to a specific pressure according to the patient's needsShape: Adapted to the human trachea to ensure effective sealing and prevent accumulation of secretions3. Proximal ConnectionProximal Tip: Standard Luer-type connection for compatibility with balloon inflation syringe and ventilation devicesPossibility to connect a pressure monitoring device to monitor balloon inflationGraduations: Graduations on the tube for precise positioning during intubation4. Sterilization and SafetyIndividually sterile packagingSingle use, reducing the risk of cross-infection and contamination

ENDOTRACHEAL TUBE WITH PVC CUFFS 8.0mm - UNIT	1. TubeType: Endotracheal tube with cuffInner diameter: 8.0 mm (about 8.0 mm inner diameter)Outer diameter: About 10.0 mmLength: 20 to 30 cmMaterial: Soft and transparent medical PVC, allowing clear observation of secretions and the tube2. CuffCuff type: Pressure-controlled cuff to ensure optimal airway sealing and prevent leakage during ventilationCuff material: Soft and smooth PVC, ensuring low friction to minimize the risk of tracheal irritationCuff volume: Pre-filled or can be inflated to a specific pressure according to the patient's needsShape: Adapted to the human trachea to ensure effective sealing and prevent accumulation of secretions3. Proximal ConnectionProximal Tip: Standard Luer-type connection for compatibility with balloon inflation syringe and ventilation devicesPossibility to connect a pressure monitoring device to monitor balloon inflationGraduations: Graduations on the tube for precise positioning during intubation4. Sterilization and SafetyIndividually sterile packagingSingle use, reducing the risk of cross-infection and contamination

ENDOTRACHEAL TUBE WITH PVC CUFFS 3.0mm - UNIT	1. TubeType: Endotracheal tube with cuffInner diameter: 3.0 mm (about 3.0 mm inner diameter)Outer diameter: About 4.0 mmLength: 12 to 20 cmMaterial: Soft and transparent medical PVC, allowing clear observation of secretions and the tube2. CuffCuff type: Pressure-controlled cuff to ensure optimal airway sealing and prevent leakage during ventilationCuff material: Soft and smooth PVC, ensuring low friction to minimize the risk of tracheal irritationCuff volume: Pre-filled or can be inflated to a specific pressure according to the patient's needsShape: Adapted to the human trachea to ensure effective sealing and prevent accumulation of secretions3. Proximal ConnectionProximal Tip: Standard Luer-type connection for compatibility with balloon inflation syringe and ventilation devicesPossibility to connect a pressure monitoring device to monitor balloon inflationGraduations: Graduations on the tube for precise positioning during intubation4. Sterilization and SafetyIndividually sterile packagingSingle use, reducing the risk of cross-infection and contamination

ENDOTRACHEAL TUBE WITH PVC CUFFS 4.0mm - UNIT	1. TubeType: Endotracheal tube with cuffInner diameter: 4.0 mm (inner diameter measured at the tube)Outer diameter: About 5.0 mmLength: 20 to 30 cmMaterial: Soft and transparent medical PVC, allowing clear observation of secretions and the tube2. CuffCuff type: Pressure-controlled cuff to ensure optimal airway sealing and prevent leakage during ventilationCuff material: Soft and smooth PVC, ensuring low friction to minimize the risk of tracheal irritationCuff volume: Pre-filled or can be inflated to a specific pressure according to the patient's needsShape: Adapted to the human trachea to ensure effective sealing and prevent accumulation of secretions3. Proximal ConnectionProximal Tip: Standard Luer-type connection for compatibility with balloon inflation syringe and ventilation devicesPossibility to connect a pressure monitoring device to monitor balloon inflationGraduations: Graduations on the tube for precise positioning during intubation4. Sterilization and SafetyIndividually sterile packagingSingle use, reducing the risk of cross-infection and contamination

ENDOTRACHEAL TUBE WITH PVC BALLOON 5.0mm - UNIT	1. TubeType: Endotracheal tube with cuffInternal diameter: 5.0 mm (measured at the tube)External diameter: About 6.0 mmLength: 25 to 30 cmMaterial: Soft and transparent medical PVC, allowing clear observation of secretions and the tube2. CuffCuff type: Pressure-controlled cuff to ensure optimal airway seal and prevent leakage during ventilationCuff material: Soft and smooth PVC, ensuring low friction to minimize the risk of tracheal irritationCuff volume: Pre-filled or can be inflated to a specific pressure according to the patient's needsShape: Adapted to the human trachea to ensure effective seal and prevent accumulation of secretions3. Proximal ConnectionProximal Tip: Standard Luer-type connection for compatibility with balloon inflation syringe and ventilation devicesPossibility to connect a pressure monitoring device to monitor balloon inflationGraduations: Graduations on the tube for precise positioning during intubation4. Sterilization and SafetyIndividually sterile packagingSingle use, reducing the risk of cross-infection and contamination

GASTRIC TUBE CH12-PVC UU - UNIT -	1. ProbeType: CH12 gastric tubeDiameter: CH12 (12 French), corresponding to an outer diameter of approximately 4 mmLength: 90 to 120 cmMaterial: Soft and transparent PVC, facilitating observation of the probe and the aspirated or drained contentsBiocompatible, minimizing the risk of allergies and tissue irritationNon-latex to avoid the risk of latex allergies2. Design and StructureShape: Smooth and flexible, for easy passage through the esophagus and stomach without risk of traumaRounded edges, reducing the risk of irritation of the internal mucous membranesDistal end: Closed with 4 side holesGraduated markings on the probe to aid in correct insertion and positioningProximal tip: Luer connection for easy attachment to drainage devices, suction syringe or feeding devicesExternal fixation option, to hold the probe in place after insertion3. Sterilization and safetyIndividually sterile packagingSingle use, to avoid the risk of cross-contamination and ensure optimum safety

GASTRIC TUBE CH14-PVC UU - UNIT -	1. ProbeType: CH12 gastric tubeDiameter: Caliber (CH): CH14 (14 Fr), which corresponds to a diameter of 4.67 mmLength: 90 to 120 cmMaterial: Soft and transparent PVC, facilitating the observation of the probe and the aspirated or drained contentsBiocompatible, minimizing the risk of allergies and tissue irritationNon-latex to avoid the risk of latex allergies2. Design and StructureShape: Smooth and flexible, for easy passage through the esophagus and stomach without risk of traumaRounded edges, reducing the risk of irritation of the internal mucous membranesDistal end: Closed with 4 side holesGraduated markings on the probe to aid in correct insertion and positioningProximal tip: Luer connection for easy attachment to drainage devices, suction syringe or feeding devicesExternal fixation option, to hold the probe in place after insertion3. Sterilization and safetyIndividually sterile packagingSingle use, to avoid the risk of cross-contamination and ensure optimum safety

GASTRIC TUBE CH16-PVC UU - UNIT -	1. ProbeType: CH12 gastric tubeCaliber (CH): CH16 (16 Fr), i.e. a diameter of 5.33 mm.Length: 90 cmMaterial: Soft and transparent PVC, facilitating the observation of the probe and the aspirated or drained contentsBiocompatible, minimizing the risks of allergies and tissue irritationNon-latex to avoid the risk of latex allergies2. Design and StructureShape: Smooth and flexible, for easy passage through the esophagus and stomach without risk of traumaRounded edges, reducing the risk of irritation of the internal mucous membranesDistal end: Closed with 4 side holesGraduated markings on the probe to aid in correct insertion and positioningProximal tip: Luer connection for easy attachment to drainage devices, suction syringe or feeding devicesExternal fixation option, to hold the probe in place after insertion3. Sterilization and safetyIndividually sterile packagingSingle use, to avoid the risk of cross-contamination and ensure optimum safety

GASTRIC TUBE CH18-PVC UU - UNIT -	1. ProbeType: CH12 gastric tubeCaliber (CH): CH18 (18 Fr), i.e. a diameter of 6.0 mm.Length: 90 cmMaterial: Soft and transparent PVC, facilitating observation of the probe and the aspirated or drained contentsBiocompatible, minimizing the risk of allergies and tissue irritationNon-latex to avoid the risk of latex allergies2. Design and StructureShape: Smooth and flexible, for easy passage through the esophagus and stomach without risk of traumaRounded edges, reducing the risk of irritation of the internal mucous membranesDistal end: Closed with 4 side holesGraduated markings on the probe to aid in correct insertion and positioningProximal tip: Luer connection for easy attachment to drainage devices, suction syringe or feeding devicesExternal fixation option, to hold the probe in place after insertion3. Sterilization and safetyIndividually sterile packagingSingle use, to avoid the risk of cross-contamination and ensure optimum safety

NUTRITIONAL NASAL PROBE CH4 PVC UU - UNIT -	1. Dimensions and ShapeCaliber (CH): CH4 (4 Fr), corresponding to a diameter of 1.33 mm.Length: Generally 90 cmShape: Flexible and curved, allowing comfortable insertion into the nasal passages and easy management.Extremity: The end of the probe is rounded to minimize irritation of the nasal and gastric mucous membranes and facilitate passage through the digestive tract.2. MaterialMaterial: Made of medical PVC (polyvinyl chloride), a flexible, transparent and biocompatible material.Properties:Soft and flexible,Transparency, allowing easy observation of the contents of the probe and the movement of fluids.Chemical resistant, which ensures compatibility with body fluids and nutritional substances.Designed for single use to prevent the risk of infection and contamination.Luer-lock or other standard connector, allowing secure attachment to feeding or suction devices.Each probe is individually packaged in a sterile bag to ensure protection against contamination.
NUTRITIONAL NASAL PROBE CH8 PVC UU - UNIT -	1. Dimensions and ShapeCaliber (CH): CH8 (8 Fr), corresponding to a diameter of 2.67 mm.Length: Generally 90 cmShape: Flexible and curved, allowing comfortable insertion into the nasal passages and easy management.Extremity: The end of the probe is rounded to minimize irritation of the nasal and gastric mucous membranes and facilitate passage through the digestive tract.2. MaterialMaterial: Made of medical PVC (polyvinyl chloride), a flexible, transparent and biocompatible material.Properties:Soft and flexible,Transparency, allowing easy observation of the contents of the probe and the movement of fluids.Chemical resistant, which ensures compatibility with body fluids and nutritional substances.Designed for single use to prevent the risk of infection and contamination.Luer-lock or other standard connector, allowing secure attachment to feeding or suction devices.Each probe is individually packaged in a sterile bag to ensure protection against contamination.

OXYGEN PROBE CH10-40CM-PVC UU - UNIT -	Quality standardsEN 13544-2, 2002, +A1 2009 Respiratory therapy equipment - Part 2: Tubing and connectorsISO 15001, 2010, edition 2, (confirmed 2022) Anaesthesia and respiratory equipment - Oxygen compatibility Technical specificationsPVCOpen, atraumatic distal (patient) end with 6 to 12 side portsProximal end with straight conical connector allowing the probe to be connected to an oxygen supply tube of any diameter (e.g. tapered male tip). This proximal end also includes a piece of polyether foam.Sterile, single patientDimensions:Diameter: CH 10Length: ± 40 cm Packaging and labelingSterile single pack in peelable pouch
OXYGEN PROBE CH12-40CM PVC UU - UNIT -	Quality standardsEN 13544-2, 2002, +A1 2009 Respiratory therapy equipment - Part 2: Tubing and connectorsISO 15001, 2010, edition 2, (confirmed 2022) Anaesthesia and respiratory equipment - Oxygen compatibility Technical specificationsPVCOpen, atraumatic distal (patient) end with 6 to 12 side portsProximal end with straight conical connector allowing the probe to be connected to an oxygen supply tube of any diameter (e.g. tapered male tip). This proximal end also includes a piece of polyether foam.Sterile, single patientDimensions:Diameter: CH 12Length: ± 40 cm Packaging and labelingSterile single pack in peelable pouch

OXYGEN PROBE CH14-40CM PVC UU - UNIT -	Quality standardsEN 13544-2, 2002, +A1 2009 Respiratory therapy equipment - Part 2: Tubing and connectorsISO 15001, 2010, edition 2, (confirmed 2022) Anaesthesia and respiratory equipment - Oxygen compatibility Technical specificationsPVCOpen, atraumatic distal (patient) end with 6 to 12 side portsProximal end with straight conical connector allowing the probe to be connected to an oxygen supply tube of any diameter (e.g. tapered male tip). This proximal end also includes a piece of polyether foam.Sterile, single patientDimensions:Diameter: CH 14Length: ± 40 cm Packaging and labelingSterile single pack in peelable sachet
CH20 RECTAL PROBE - UNIT	Dimensions and ShapeCaliber: CH20 (6.67 mm outer diameter).Length: Approximately 40 cm to 50 cm, facilitating insertion while limiting discomfort.Distal end: Rounded and atraumatic to minimize the risk of damage to the rectal mucosa.Lateral perforations (1 to 2) allowing good evacuation of gases and liquids.Proximal end: Tapered or luer-lock tip allowing easy connection with a collector or irrigation system.
CH22 RECTAL PROBE - UNIT	Dimensions and ShapeCaliber: CH22 (outer diameter of 7.33 mm)Length: Approximately 40 cm to 50 cm, facilitating insertion while limiting discomfort.Distal end: Rounded and atraumatic to minimize the risk of damage to the rectal mucosa.Lateral perforations (1 to 2) allowing good evacuation of gases and liquids.Proximal end: Tapered or luer-lock tip allowing easy connection with a collector or irrigation system.

CH28 RECTAL PROBE - UNIT	Dimensions and ShapeCaliber: CH20 (6.67 mm outer diameter).Length: Approximately 40 cm to 50 cm, facilitating insertion while limiting discomfort.Distal end: Rounded and atraumatic to minimize the risk of damage to the rectal mucosa.Lateral perforations (1 to 2) allowing good evacuation of gases and liquids.Proximal end: Tapered or luer-lock tip allowing easy connection with a collector or irrigation system.
CH30 RECTAL PROBE - UNIT	Dimensions and ShapeCaliber: CH20 (6.67 mm outer diameter).Length: Approximately 40 cm to 50 cm, facilitating insertion while limiting discomfort.Distal end: Rounded and atraumatic to minimize the risk of damage to the rectal mucosa.Lateral perforations (1 to 2) allowing good evacuation of gases and liquids.Proximal end: Tapered or luer-lock tip allowing easy connection with a collector or irrigation system.
CH32 RECTAL PROBE - UNIT	Dimensions and ShapeCaliber: CH20 (6.67 mm outer diameter).Length: Approximately 40 cm to 50 cm, facilitating insertion while limiting discomfort.Distal end: Rounded and atraumatic to minimize the risk of damage to the rectal mucosa.Lateral perforations (1 to 2) allowing good evacuation of gases and liquids.Proximal end: Tapered or luer-lock tip allowing easy connection with a collector or irrigation system.
2-WAY FOLEY VESICAL CATHETER BALLOON 30ML CH 22 UU- UNIT	• Foley bladder catheters must be made of silicone latex, straight cylindrical, 40 cm long, 2-way with a 30 ml balloon. All catheters must be - single use; - sterile and non-pyrogenic; - Packaged in an individual sterility protector in the form of a peelable sachet bearing the regulatory information and all the indications for use

2-WAY FOLEY VESICAL CATHETER BALLOON 30ML CH 24 UU - UNIT	• Foley bladder catheters must be made of silicone latex, straight cylindrical, 40 cm long, 2-way with a 30 ml balloon. All catheters must be - single use; - sterile and non-pyrogenic; - Packaged in an individual sterility protector in the form of a peelable sachet bearing the regulatory information and all the indications for use
2-WAY FOLEY VESICAL CATHETER BALLOON 30ML CH16 UU - UNIT -	• Foley bladder catheters must be made of silicone latex, straight cylindrical, 40 cm long, 2-way with a 30 ml balloon. All catheters must be - single use; - sterile and non-pyrogenic; - Packaged in an individual sterility protector in the form of a peelable sachet bearing the regulatory information and all the indications for use
2-WAY FOLEY VESICAL CATHETER BALLOON 30ML CH18 UU - UNIT -	• Foley bladder catheters must be made of silicone latex, straight cylindrical, 40 cm long, 2-way with a 30 ml balloon. All catheters must be - single use; - sterile and non-pyrogenic; - Packaged in an individual sterility protector in the form of a peelable sachet bearing the regulatory information and all the indications for use
2-WAY FOLEY VESICAL CATHETER BALLOON 30ML CH20 UU - UNIT	• Foley bladder catheters must be made of silicone latex, straight cylindrical, 40 cm long, 2-way with a 30 ml balloon. All catheters must be - single use; - sterile and non-pyrogenic; - Packaged in an individual sterility protector in the form of a peelable sachet bearing the regulatory information and all the indications for use

3-WAY FOLEY VESICAL CATHETER BALLOON 30ML CH18 UU - UNIT	• Foley bladder catheters must be made of silicone latex, straight cylindrical, 40 cm long, 3-way with a 30 ml balloon. All catheters must be - single use; - sterile and non-pyrogenic; - Packaged in an individual sterility protector in the form of a peelable sachet bearing the regulatory information and all the indications for use
3-WAY FOLEY VESICAL CATHETER BALLOON 30ML CH20 UU - UNIT	• Foley bladder catheters must be made of silicone latex, straight cylindrical, 40 cm long, 3-way with a 30 ml balloon. All catheters must be - single use; - sterile and non-pyrogenic; - Packaged in an individual sterility protector in the form of a peelable sachet bearing the regulatory information and all the indications for use
3-WAY FOLEY VESICAL CATHETER BALLOON 30ML CH22 UU - UNIT	• Foley bladder catheters must be made of silicone latex, straight cylindrical, 40 cm long, 3-way with a 30 ml balloon. All catheters must be - single use; - sterile and non-pyrogenic; - Packaged in an individual sterility protector in the form of a peelable sachet bearing the regulatory information and all the indications for use
FOLEY CH8 BLADDER CATHETER - PEDIATRIC - UNIT	• Foley bladder catheters must be made of silicone latex, straight cylindrical, 40 cm long, 2 or 3-way with a 30 ml balloon. All catheters must be - single use; - sterile and non-pyrogenic; - Packaged in an individual sterility protector in the form of a peelable sachet bearing the regulatory information and all the indications for use

ADHESIVE TAPE 18CMX5M - ROLL -	The 18 cm x 5 m perforated adhesive plasters must meet the following characteristics: - roll of woven adhesive plaster with zinc oxide, flesh-coloured or white, made of a cellulose acetate backing that can be cut by hand - coated on one side only with a zinc oxide adhesive mass with normal skin tolerance, and with significant and prolonged adhesiveness, easy to handle for the user. Any unsatisfactory adhesiveness will not be accepted. - perforated, hydrophobic, with serrated edge, - with embossed polyethylene protector, - and packaged in individual protective packaging with all the instructions for use.
STERILE TRANSFUSER UU - UNIT	Technical characteristics: Main Components: Tubing: Material: Soft, transparent medical PVC, allowing visualization of blood flow and easy handling Length: Usually between 150 cm and 200 cm, depending on clinical needs Internal diameter (lumen): Approx. 1.2mm to 3mm, suitable for blood product transfusion Filter: Equipped with an integrated filter to eliminate micro-aggregates of cells or other impurities that may be present in the blood Filter pore size: Typically between 170 and 260 microns Connectors: Luer-lock connectors on each end to ensure a secure connection between the transfuser, blood bags, and catheters or needles Connection with blood bags: Often a specific connection to fit standardized blood bags Non-return valve: Helps ensure there is no blood backflow or cross contamination Flow Control: Flow regulator: Equipped with a manual regulator to control the transfusion flow rate, allowing for safe and precise administration. Additional accessories: Infusion needle: Included in some models to facilitate infusion into peripheral veins
REDON TUBE WITH 400ML BOTTLE - UNIT	<u>Redon tube</u> Material: Soft, transparent, latex-free medical PVC. Length: 100 cm to 150 cm depending on the model. Diameter: Available in several sizes (CH8 to CH18). Distal end: Laterally perforated (2 to 4 holes) for optimal suction.

	Atraumatic tip to reduce the risk of tissue irritation. Proximal end: Tapered connector ensuring secure attachment to the bottle. Compatible with other drainage systems. Collection Bottle (400 ml Reservoir) Material: Rigid, unbreakable, transparent polypropylene. Capacity: 400 ml, allowing prolonged drainage. Vacuum system: Allows continuous passive suction for efficient liquid evacuation. Vacuum indicator to monitor the depression. Visible graduations to monitor the volume of liquid collected. Anti-reflux valve to prevent secretions from returning to the patient. Airtight cap allowing safe disposal after use.
ANTIBACTERIAL FILTER	1. Technical characteristics Filtration and Performance Bacterial filtration efficiency (BFE): ≥ 99.99% Viral filtration efficiency (VFE): ≥ 99.99% Low resistance to airflow, allowing breathing without excessive strain. Particle filtration capacity ≥ 0.3 µm, guaranteeing optimal protection. Materials Filter media: Polypropylene membrane, guaranteeing high-performance filtration. Housing: Latex-free, biocompatible, durable, rigid medical plastic. Non-toxic materials, compliant with ISO 10993 biocompatibility standards. Catheter Mount (Flexible Extension) Material: Soft, transparent medical PVC, latex-free. Length: 15 cm to 30 cm depending on the model. Standardized connectors: Input: 22mm M / 15mm F Output: 22mm F / 15mm M Flexible or accordion joint allowing better adaptation to patient movements and reducing the risk of accidental disconnection. Single use, avoiding any cross contamination.
ELECTRODE FOR ECG-	Dimensions and Compatibility Diameter: 40mm to 55mm (standard for most ECG monitors). Shape: Round or oval, suitable for different areas of the body. Connection: Snap: Compatible with most ECG cables.

	Clip or tab: For some specific models. Materials Contact surface: Ag/AgCl (Silver Chloride/Silver) film for better signal conduction. Hypoallergenic medical adhesive: Latex free, avoiding allergic reactions. Strong grip to avoid artifacts during movement. Foam or non-woven fabric backing: Foam: Fluid resistant, suitable for long monitoring periods. Non-woven: More flexible and comfortable for sensitive skin.
FL 250G ULTRASOUND CONTACT GEL - UNIT -	Type: Medical contact gel, often used for ultrasound and other examinations requiring efficient signal transmission.Formulation: Based on carboxymethylcellulose (CMC), glycerin or other moisturizing agentsNon-irritating, hypoallergenic to reduce the risk of allergies or skin irritationViscosity: Thick or moderate, allowing easy application while avoiding excessive dripping during proceduresPH: Adjusted to be neutral (approximately pH 6.5 to 7.5) to be gentle on the skin and avoid irritationProperties: Good wave conductivity (used for ultrasound or ECG)Does not contain particles or substances that may affect examination resultsEase of application and cleaning after the examinationNon-greasy and non-comedogenic to avoid unwanted residue on the skin
ECG GEL - FLC/250ML	Composition: - demineralized water: ≥95% - softening polymers - preservative - humectants They must be compatible with all types of ECG electrodes, non-irritating, easy to clean.
RADIO - FILM 18X24CM -	X-ray films must be manufactured according to ISO 9002 or EN 46002 standards. They must be provided with interleaves or tropicalized (with supporting certificate).
RADIO - FILM 20X40CM -	X-ray films must be manufactured according to ISO 9002 or EN 46002 standards. They must be provided with interleaves or tropicalized (with supporting certificate).
RADIO - FILM 24X30CM -	X-ray films must be manufactured according to ISO 9002 or EN 46002 standards. They must be provided with interleaves or tropicalized (with supporting certificate).

RADIO - FILM 30X40CM -	X-ray films must be manufactured according to ISO 9002 or EN 46002 standards. They must be provided with interleaves or tropicalized (with supporting certificate).
RADIO - FILM 35X35CM -	X-ray films must be manufactured according to ISO 9002 or EN 46002 standards. They must be provided with interleaves or tropicalized (with supporting certificate).
RADIO - FILM 35X43CM -	X-ray films must be manufactured according to ISO 9002 or EN 46002 standards. They must be provided with interleaves or tropicalized (with supporting certificate).
NITRILE GLOVES SIZE M	Material 100% nitrile (latex free, ideal for people with latex allergies). Increased resistance to chemicals, punctures and tears. Average thickness: 0.08 mm to 0.12 mm (depending on the manufacturer). Dimensions and Size Size M (Medium) Palm width: Approx. 85-105mm. Length: Minimum 240 mm (according to EN 455 standard). Anatomically shaped, ensuring a good fit and optimal comfort. Properties and Design Powder-free (limits the risk of contamination and skin irritation). Textured surface on fingers for better grip and grip. Ambidextrous, allowing easy and quick donning. Rolled edge for added strength and easier donning

Appendix No. 13: TECHNICAL SPECIFICATIONS OF DENTISTRY PRODUCTS

DESIGNATION	SPECIFICATIONS
Dental needles: 27 G 16mm x 0.40, and/or short needle 30 G (0.3 x21)	Sterile single-use needles, triple bevel, silicone tube 27G, 30G
Mepivacaine without Adrenaline	Injectable solution for dental use (cartridge): 30 mg/ml
Anesthetics with A: mepivacaine / lidocaine 2% (cartridge)	Injectable solution for dental use (cartridge): 20 mg/ml+12.5 µg/ml
Root canal antiseptic solution for dental use (ml)	Solution - Bottle
Assorted Channel Pins (No. 15—40)	Octagonal handle with diameter identification, ISO color coding
Sodium hypochlorite 3% 500ml bottle	Solution - Bottle
Light-curing composite for anterior teeth A2, A3	Syringe A2, or syringe A3, Complete kit
Light-curing composite for posterior teeth	Syringe A2, or syringe A3, Complete kit
Oxygenated Water 20vol 125 ml bottle	Solution 10 volumes, 20 volumes - Bottle
Eugeunol bottle 100 ml	Solution - 125 ml bottle
Round Diamond Turbine Cutter	Ball, No. 1, piece
Cylindrical Diamond Turbine Cutters	Cylindrical, No. 1, part
Lentulo for contra angle, for dental use 25 mm	21mm standard
Zinc oxide box of 500 grams	Extra Pure Powder - Box/500mg
Pulp devitalizer, non-arsenic for dental use, box of 6 grams	6.5g jar
Abrasive strips	Fine granularity
Dental nerve puller 2mm set of 12 pieces	Assorted numbers 21mm, 25mm
Glass ionomer for filling Type 1	Powder + liquid
Glass ionomer for filling Type 3	Powder + liquid
Hydrophilic compress 10cmx10cm non-woven sterile	Non-woven, sterile, 30 g, 4 ply, 7.5 cm x 7.5 cm, 10 cm x 10 cm
Hydrophilic compress 10cmx10cm non-woven non-sterile	Non-woven, non-sterile, 30 g, 4 ply, 7.5 cm x 7.5 cm, 10 cm x 10 cm
Non-sterile latex examination gloves	Powder-free, non-sterile, ambidextrous latex. Size S, M, L

3-ply Class I surgical masks	3 folds, adjustable nose bar, two elastic bands. High filtration Class I
3-ply Class II surgical masks	3 folds, adjustable nose bar, two elastic bands. High filtration Class II
Fandio (bottle) or cold disinfectant	Virucidal, bactericidal solution - Bottle
70° alcohol 500ml bottle	Bottle/500 ml
Dental Etching Syringe 5ml	Syringe
Dental bonding 5ml bottle	Bottle/4 ml
Gutta percha	Assorted Diameters – Box/120 units
Metal matrix with matrix holder for dental use (cm)	Unit
Micro lathe handpiece lubricant for rotating equipment 500ml bottle	Spray - Bottle
Calcium hydroxide for dental use or Dycal 2g syringe	Paste - Tube
Tenon screw for posterior/anterior tooth (Box)	Kit
Endometasone, Root canal paste for dental use 42g	Paste - Tube
Iodoform paste 15g	Yellow powder ready to use