

ANNEX – 1

BID NO. : DHS/M/SS/WW/1/24
DATE OF ISSUE : 06TH NOVEMBER 2023
CLOSING DATE & TIME : 18TH DECEMBER 2023 AT 11.00 HOURS SRI LANKA TIME

ORDER LIST NUMBER: 2024/SPC/N/C/S/00027

Item No	SR No	Item	Qty	Delivery	Bid Bond value	
					LKR	USD
01	12704601	<p>Proximal Femoral Nail Anti-rotation system for 50 patients. Each unit of PFNA should consist of the following and all should be included to form a complete set.</p> <ol style="list-style-type: none"> 1. Proximal Femoral Nails Anti Rotation (PFNA) from size 170mm-420mm to include all long PFNA nails. 2. Spiral blades for varying sizes. 3. Locking Bolt 02 Nos. for each unit starting from 28mm-60mm. 4. End cap. <p>AO compatible. Each 50 set should be supplied with compatible free instrument set (SR No. 21209312) comprising;</p> <ol style="list-style-type: none"> (a) PFNA nail insertion instrument set. (b) Spiral blade insertion instrument set. (c) Distal locking instrument set for oblique and transverse locking. <p>Important: The supplier should be able to supply the commonly used sizes and exchange implants on demand from the hospitals. Packing: 1 set</p>	70 sets	70-Jan/2024	7,083,733.00	21,834.00

Four (04) Nos. of Representative tender samples of item 1,2,3 and 4 of above listed and Sample Catalogue/ Literature should be submitted for bid evaluation.

Whenever a new supplier quotes, the supplier should provide samples to be tested at OT by two (02) orthopaedic surgeons. Compatible Instrument set should be available at the time of surgery.

Valid up to 10.06.2024 has to be submitted with the bid.

The Bid should be valid till 11.05.2024

Non – refundable Bid fee – Rs. 60,000.00 + taxes

N.B.

If Local Agent Commission to be paid the percentage should be clearly indicate in annex 1B.

Bid Evaluation summary sheets should be submitted with the Bid (Please refer SPC website for more details)

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

(a) Part A-General Order Conditions (GOC) of Supply

1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration from NMRA.
3. Maintaining the validity of the product registration during the period of supply (delivery schedule), obtaining import license / manufacture licensing at NMRA, is a pre-requisite for the supply of pharmaceutical items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier.

A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
5. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same, will not be entertained unless otherwise mentioned in this document.

Shelf life & Warrantees

6. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/ in case of local supplies) of the product, shall be 85% of the product shelf life specified in order/Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)
 - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for surgical items and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed 1/6th of the original product shelf life.
 - (b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 33)

Standards & Quality

7. **Standards:** In addition to Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards that are registered at National Medicines Regulatory Authority in Sri Lanka are also acceptable when no bidders have quoted for the standard specified in the item specification.
8. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the instruction pamphlet with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.
9. Any product deficient of its sub-components/accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set) shall be rejected.
10. Withdrawal from use of items due to quality failure found as manufacturer's/Supplier's fault:
 - (a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
 - (b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
 - (c). In the event of either a) or b) above, supplier shall be charged the total **cost involved for MSD, of the quality failed supplies** with 25% administrative charge of the same.
11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.
If the offered product, deviated from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology and facilities)

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling and testing charges, etc, will be recovered from the supplier.
13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

Pack size, Labeling & Packaging

14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.

- 15.** Each; innermost pack shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no. (not for pharmaceuticals), Date of Manufacture, Date of Expiry and ·STATE LOGO, of Government of Sri Lanka. Product Information Leaflet to be included with each pack.
It is essential to include and exactly match the dates of Expiry & date of Manufacture (in any form as ·Year & Month, or ·No Exp.), in the innermost pack and supplier's invoice.
(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification)
- 16.** Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ·STATE LOGO, of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure and the outer cover of the carton/box.
Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE) declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 17.** All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 18.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
Format shall be according to Code 128 or 2D standards.
Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 19.** In case of receiving goods under inappropriate packaging conditions(not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

- 20.** If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, temperature should be on or below 30° C and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

Delivery Requirements

- 21.** All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 24 on delayed deliveries, shall be applied.

22. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments **to reach Sri Lanka from 15th December to 10th January** shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
23. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below ;
- (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its latest amended delivery schedules.
- (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
24. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
- (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
25. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per condition No. 23 (regarding defaulted consignment) of the conditions of supply. As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
26. The extension of L/C's overstepping delivery schedules in the Indent/PO/its amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 23 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
27. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its amendments) under the condition No. 23, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

28. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

29. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.

The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC. Reference sample will be sent by State Pharmaceuticals Corporation (SPC) to MSD.

30 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.

31. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated by weekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 23 will not be applicable.

Common conditions

32. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

33. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision.

Abbreviations :NMRA ; National Medicines Regulatory Authority/Sri Lanka, SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division, WDN; Wharf Delivery Note.

(b) Part B-Special Order Conditions (SOC) of Supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. and SR Nos shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- All Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

Amendments of Bidding Document for Procurement of Surgical/Lab items

(1) **Clause 8**

- (a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.
- (b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

- (c) To be deleted.

(2) **Clause 12**

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) **Clause 16.6**

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) **Clause 28.0**

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in www.spc.lk Web Site)

(5) 2nd column of Annex II B amend as “FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION”

(6) Annex – 1 to be amend as follows.

SPECIMEN OF ANNEX – 1

ANNEX – 1

**BID NO/ BID REFERENCE :
(TENDER NO)**

DATE OF ISSUE :

**CLOSING DATE & TIME :
(SRI LANKAN TIME)**

ORDER LIST NO :

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond : LKR or USD to be submitted along with the Bid Bond valid till (date)

Bid validity period : Bid should be valid till (date)

Bid Document Fee :
(should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

- 1.
- 2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of 1957)
Mehewara Piyasa, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka.
Telephone (00)94-1-2335008 Fax: (00)94-11-2582495
E-mail: dqmsurgical@spc.lk or mgrsurgical@spc.lk

**DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA
AGREEMENT**

SPC Ref. No
Bid Ref.

Date :

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at, Mehewara Piyasa, 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the SPC+ which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

M/s
...business under the time, style and firm of a company duly registered and carrying business (hereinafter called the supplier+ and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART.**

AND

M/s
...business under the time, style and firm of a company duly registered and carrying business (hereinafter called the Local Agent+ and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **THIRD PART.**

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s
..... for the supply and delivery of as per the attached indent for marked SPC Dated and M/s will act as local agent of the supplier for all matters arising out of supplies here of.

NOW IT IS HEREBY AGREED AS FOLLOWS:

- 1. The following documents: .
 - (a) Conditions of Contract marked . Annex 1
 - (b) Bid Documents marked . Annex 2
 - (c) Copy of Indent marked . Annex 3

(hereinafter called ~~the~~ Contract Documents) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and ~~and~~ and ~~and~~ of State Pharmaceuticals Corporation have set their hands and Supplier and the Local Agent has placed its hand/caused its Common Seal to be affixed hereunto and to two other of the same tenor on this ~~and~~ .20~~and~~

The Common Seal of M/s (supplier)~~and~~ ... herein.

1. ..
President/Managing Director/C.E.O.

2. ..
Director

Witnesses

Signature

Name, Address and ID No./Passport No.

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The Common Seal of M/s. õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ (Local Agent) herein.

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President/Managing Director/C.E.O.

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Director

Witnesses

Signature

Name, Address and ID No./Passport No.

1. õ õ õ õ õ õ õ õ õ õ õ .

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CONDITIONS OF CONTRACT

3. FREE REPLACEMENT /REIMBURSEMENT

3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of

- 3.1.1 Short packing
- 3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
- 3.1.3 Packs which cannot be identified due to labels falling off.
- 3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.

3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 Withdrawal from use of Item due to quality failure.

- a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
- b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
- c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21. NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

