ANNEX – 1

BID NO. : DHS/SUS/WW/78/24
DATE OF ISSUE : 11TH JULY 2023
CLOSING DATE & TIME : 23RD AUGUST 2023 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka
2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
3. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price.
4. The volume of the total quantity of each item should be given in cubic meters (m^3)
5. **Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.**
6. **Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.**
7. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
9. We reserve the right to reject offers which do not comply above.
10. The offer should be valid up to 19.02.2024

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, manufacturer²s 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 surgical 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. If MSD decides to accept consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering

the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply surcharge (as clause No. 37).

6. The specifications of the product offered by the suppliers in the tender, shall match with the tender specifications for the item and **any form of alternate offers for the same, will not be entertained,** when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees

7. In respect of Non consumables; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and /or it²s sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier²s invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repair and spares, when necessary (**This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory items)**

8. 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/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed $1/6^{th}$ (one sixth) 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. 37 and footnote 01)

Standards & Quality

9. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.

10. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. 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.

Any product deficient of or incompatible with, 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.

11. Withdrawal from use of items due to quality failure found as manufacturer²s/Supplier²s 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**.**

12. 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.(refer clause No.24)

If the offered product, deviate 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.

13. 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.

14. 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.11).

15. <u>Pack size, Labeling & Packaging</u>

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.

16. In respect of bulk packs (not applicable for blister/strip packs), ³DHS´ mark shall be ;
(a). embossed or printed in case of tablets
(b). printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots **<u>or</u>** when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)**

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue Nos of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and ³STATE LOGO´ of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Non-consumables) & date of Manufacture (in any form as ³Year & Month´ or ³No Exp.´), in the innermost pack and supplier²s invoice.

18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ³STATE LOGO´ of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on 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.

19. 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.

20. 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).

21. 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

22. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30^0c +/- 2^0c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

23. Maintenance of Cold Chain;

a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer²s instructions during storage, transport and delivery.

b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized **USB Devices** for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant **WDN or copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until ±observed cold chain break² is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.

e. The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

24. In respect of the products requiring controlled temperature storage (Eg. < 25^0c, 2-25^0c, 15-20^0c/30^0c, 2-8^0c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30^0c +/- 2^0c & 75% +/- 5% RH for **AC stored** items and at 25^0c +/- 2^0c & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.12)

Delivery Requirements

25. 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. 27 on delayed deliveries, shall be applied.

26. 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.

27. 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 its² 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 charge.

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its² 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.

29. 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 supplier²s 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 No. 27 (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 other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

30. The extension of L/C²s overstepping delivery schedules in the Indent/PO/its² amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its² amendments) under the condition No. 27, 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

32. Details of Cochlear Implant Attached herewith.

33. 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.

34. 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. (applicable for all surgical items and laboratory regular items except when specified in respective order lists).

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No²s, as necessary for the surgical items (**not relevant to pharmaceutical & Laboratory items)** shall be provided with the bid document, for reference in the; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions shall be provided before signing the contract with the performance bond.

34 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.

35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly 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. 27 will not be applicable.

Common conditions

36. 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.

37. 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. **(eg. As in conditions No. 08,05,10,13)**

Abbreviations :*NMRA ; National Medicines Regulatory Authority/Sri Lanka,* SPC ; State *Pharmaceuticals Corporation, MSD; Medical Supplies Division,*

(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 No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

1. **Evaluation should be based on the supplier's recommended lifetime of the products. It should be a Major bidding criteria.**
2. **A mandatory warranty period should be considered as a major selection criteria.**
3. **The supplier should provide quoted unit prices of the recommended spare parts/accessories with labour costs and provide a breakdown of annual maintenance and service cost for the reminder of the recommended lifetime period of the product. It should be a mandatory/bidding requirement.**
4. **All accessories replacement and part replacement repairs should be free of charge on labour and material costs during the warranty period.**
5. **Labour cost and service maintenance should be free of charge after the warranty period for the remainder of the recommended lifetime.**
6. **The final selection of the product shall be based on the total life cycle cost of the product that includes the costs for service and maintenance, replacing parts and accessories in addition to the bidding price of the product.**

Sufficient quantity of samples should be forwarded for evaluation.

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.

- This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.

- 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.

- Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name And designation of the signatory) or by the representative. Representatives submit offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies – Sri Lanka.

- 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.**

Item Specifications and condition for Cochlear Implants with Accessories (SR No:13201301}

1 Approval year
- µ FDA
- µ European

Lowest approval age of implantation should be 1 year

2 Country of origin of the machine should be stated and country of origin of different component should be mentioned 3

i. Year and the country of first implantation of the quoted model.

ii. Year of first implantation in Sri Lanka

iii. Number of implanted devices worldwide, of the quoted model with annual breakdown in last five years.

iv. Number of devices implanted in Sri Lanka (to date)

v. Number of devices implanted or sold - in the country of manufacture for the last two years with breakdown.

vi. Overall failure rate of quoted model worldwide

a. Total Cumulative failure rate of the model (hard/software) should not exceed 5%. The bidder should provide documentary evidence for evaluation.

4 4.1 Bidder should be able to give a guarantee for the receiver stimulator for not less than 10 years and external speech processor for 5 years.

4.2 The bidder or its local agent should be ready to supply a suitable back up devices free of charge in the case of difficulty of insertion during implantation surgery.

4.3 The Bidder should provide depth gauge, free of charge in case, such device is needed at the time of the surgery

S Device Receiver Stimulator

5.1 Should contain not less than 12 number of intra cochlear stimulation channels/electrodes.

5.2 Material used should be titanium. In the absence of titanium, ceramic implants will be considered.

5.3 MRI compatibility with and without magnet should be stated, separately.

5.4 Manufacturer/bidder should provide the details about the features / strategies used to minimize intra cochlear damage during insertion if any.

5.5 Intra operative monitoring should be a feature of the quoted model

5.6 Also, should state

- ÅDiameter and the length of electrode.
- ÅRequirement for bony well (excavation) with suggested depth and diameter
- ÅAbility of removal and reinsertion of magnet for MRI imaging
- Å Electronic stimulation features - such as stimulation rate, modes & Strategies with any added advantages (please provide documentary evidence/proof)
- ÅPossibility of Intra operative monitoring/Mapping
- ÅThe compatibility with variety of external speech processors specially the compatibility with future improved speech processors (i.e. Possibility for upgrading without changing the receiver stimulater)

6 Device - speech processor

6.1 Mention the type -BTE type preferred and, BW is not acceptable.

6.2 Speech processor should have at least Two Microphones to enable better speech understanding in noise. Describe the speech processor strategy used indicating advantages (Please provide documentary evidence/Proof)

6.3 Batteries - type used, changing period and usable period before recharging, should be mentioned .

6.4 Minimum number of two rechargeable batteries should be supplied with the quoted model.

6.5 Availability of Remote control should be mentioned.

6.6 Water proof/ resistance features if any

6.7 Child friendly features if any

07 Local supplier/agent should supply following details/facilities

07.1 Name & contact details of the local agent with relevant certificates

07.2 Number of Devices failure locally and supply of new implants for re - implantation, free of charge for such cases during last five years

07.3 Intra operative monitoring should be done free of charge

07.4 Bidder should provide minimum of 8 post-operative therapy/ mapping sessions free of charge (for each patient) within a period of not less than two years.

07.5 Qualified professionals for mapping and therapy should be available with the supplier/ local agent. Please indicate number of professionals relevant to cochlear implantation with their names and qualifications (ie. Audiologists, speech therapists, engineers etc)

07.6 Bidder should maintain a registry of patients who undergo implantation surgery.

08 Bidder should keep mapping equipment free of charge and should provide mapping and therapy at the hospital where the implant surgeries are performed.

09 Bidder should provide country wide availability of rehabilitation centers in all provinces and should provide their network with addresses where mapping/therapy sessions can be arranged, including the names and qualifications of the personal who perform such work.

10 All necessary training for cochlear implant team should be provided.

11 Soft copy of power point presentation should be provided with the quotation including the equipments, maintenance, implantation procedure and other relevant information.

12 Bidder should be able to provide additional information/ power point presentation if required.

13 The successful bidder should agree to provide Auditory Verbal Therapy (AVT) for at least twelve (12) sessions for a period of two years for all recipients free of charge either in government hospital or private institution. Therapists should have minimum qualification of a bachelor degree in speech and hearing from a recognized university and a special training on auditory Verbal Therapy. (Documentary proof in this regard shall be provided by the successful bidder for at least one therapist in each therapy center.)

14 The successful bidder should agree to translate the owner's manual of the equipment fully including the graphics to Sinhala and Tamil languages as it appears in the English version.

15 The successful bidder should design a quick user guide extracting the most important user instructions from the manual in Sinhala and Tamil languages to be distributed to all the recipients in addition to the user manual.

16 The successful bidder should design a review format in accordance with the format given by the Ministry of Health

& Indigenous Medical Services as an attachment to the translated user manual and distribute to all recipients.

17 The successful bidder should provide the prices of all accessories and spare parts of the equipment for 5 years in USO.

18 The successful bidder shall design and print above three documents mentioned in clause No.14,15 & 16 in accordance with the instructions of the Ministry of Health & Indigenous Medical Services.

19 The successful bidder should maintain a hotline with a knowledgeable person for the recipients to contact and obtain any information.

20 The tender will be awarded in portions only upon successful completion of all above conditions.

21 Ministry of Health will review the progress using the document mentioned in clause 6 above on the already awarded portion of the total quantity and has the right to decide on awarding the balance based on the performance of the bidder.

22 The successful bidder should agree to provide (at least eight sessions of) mapping for a period of two years for all recipients free of charge either in the Government hospital or private institution by an audiologist specially trained for this purpose. (Documentary proof in this regard shall be provided by the successful bidder)

23 Life cycle costing method for procuring of Cochlear Implant as required to replace spare parts of Cochlear implant after warranty period and that spare parts are machinery compatible.

24 When there is a request for spare parts of Cochlear implant from the hospitals then the supplier should quote/provide all compatible spare parts with the prices spare parts within 6 months. In the violation of that conditions by the supplier will be considered in any subsequent tender for Cochlear Implants

25 Bidder should provide loaner machine at least within two weeks if the repair cannot be completed within two weeks.

BID NO: DHS/SUS/WW/78/24 CLOSING ON : 23.08.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/S/00199

ITEM NO	SR NO	ITEM	QTY Nos.	DELIVERY	Bid Bond value (LKR)
1	13201301	Hearing Aid, Cochlear type implant with accessories. (limited for named patients) (Please refer attached conditions)	140	70-Jun/2024 70-Oct/2024	2,910,550.00

Packing: 1 Nos.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value mentioned in the item list. Bid Bond should be submitted with valid up to 20.03.2024 together with the tender

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

1. Page 10 Condition No. 20. a
   Representative samples in respect of items offered should be submitted to reach SPC on or before the closing time on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

Contract:
The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.

A non refundable fee of Rs. 35,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

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

Annex VI

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)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA
AGREEMENT

SPC Ref. No Date :
Bid Ref.

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 é ..
…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 é ..
…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 é é é é é é
é for the supply and delivery
ofé as per the attached indent for é é é é é é marked
SPC é é é é é é é é é é é é é . Dated é é é é é é é é é é é é é and M/s
é 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 ñthe Contract Documentsò) 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 é é é é é é é é é and é é é é é é é é é é . 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 é é é é é .20é

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

1. ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ..

President/Managing Director/C.E.O.

2. ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ..

Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

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

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

é é é é é é é é é é é é é é é .
Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

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 itôs 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.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

hereto é)
é .)
é .)
é .)

Authorized signatory

Authorized signatory

Witnesses

Signature	Name, Address and ID No
1……..	**……**
2……	**……**

DR/ns