ANNEX – 1

BID NO. : DHS/L/WW/102/25
DATE OF ISSUE : 15.01.2025
CLOSING DATE & TIME : 24.02.2025 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

1. Offers should be accompanied with the original of valid registration certificate/any **Subsequent renewal certificates where applicable** or **a copy certified by an Attorney at law**, **of aforesaid document** 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. **A break-up of** 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 (into FOB and freight]} Colombo basis. **Only** 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 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 23.08.2025

GENERAL CONDITIONS OF SUPPLY FOR SPC ORDERS – APPLICABLE FOR LABORATORY ITEMS

(a) General (Product & Consignments)

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 or waiver of registration from NMRA.

3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory 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 a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) 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% surcharge 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 penalty (as clause No. 37).

6. 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 will not be entertained.

Shelf life & Warrantees

7. ~~In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or it's sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.~~

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 in case of local supplies) of the product, shall be 85% of the shelf life requested (specified in order/Indent/PO).
In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37).
When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 24 months.

Standards & Quality

9. ~~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.~~

10. ~~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.~~

11. Withdrawal from use of items due to quality failure found as manufacturer'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 surcharged the total **cost involved for MSD, of the quality failed supplies** with 25% administrative surcharge 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 MRI, 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 & 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 & testing charges, etc, will be recovered from the supplier.

14. Consignments supplied to MRI 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).

Pack size, Labeling & Packaging

15. 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), "DHS" 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 quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)~~

17. ~~Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, 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.~~
~~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.~~

18. 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, 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 manufacturer's 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 **WDNor copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' 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 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.

28. (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.

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 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 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 adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

30. 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. 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/its' 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. 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.

33. 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 regular category of laboratory items, when specified in respective order lists).
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.

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[6] 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 clause 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)**

Special Conditions

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

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

(I) 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.

Demurrage / additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.

(II) 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.

(III) 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.

(IV) 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.

(V) 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.

(VI) The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (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.

(VII) 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.

(VIII) 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**.**

(IX) Procurement Committee has the authority to decide whether pre-shipment/pre delivery / post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.

(X) The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and Invoice**.**

(XI) a) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE).

b) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the products to be procured is received by the PE.

(XII) Supplier shall submit the signed contract within 14 days of receiving of the contract agreement from SPC.

(XIII) The below mentioned documents (the original or copies certified by the attorney at law) should be submitted along with copy documents to SPC.

1. **A certified copy of the Certificate of Analysis/warranty**
2. **A certified copy of the Customs declaration**
3. **Original of the Import License**
4. **Original of the Customs Assessment Notice**
5. **Certificate copy of NMRA or WOR.**

***Note :* A certified copy of Business registration Certificate (by an Attorney at low) should be submitted with the offer**

Special –Order Conditions –HLA Histocompatibility Reagents

1. All items to be air freighted and residual shelf lie of the item should be at least 12 months ahead from the date of receipt of reagents in Sri Lanka. In circumstances here the residual shelf life is limited to <12 months (such as manufacturer recommended maximum shelf life is limited as the nature of reagents or production run), the rationale should be provided as reasoned by the manufacturer.

2. Reagents are preferred to contain the certificate of use in the country of origin with one or more of the following criteria.

    1) FDA and/or CE
    2) WHO certification
    3) End user evaluation certificate for the product and /or evidence of registration on one or more of the following countries; USA, UK, France, Germany, Canada, New Zealand, Australia or countries following equitable quality standards.

    4) Reagents are with RUO or IUO licensing considered when no equivalent products with IVD and /or CE certification is not offered and/or accompanying a documentation proving evidence (E.g. Widely acclaimed, peer reviewed publications or user reference amounting to wide usage) of specific benefit for the tests intended (to be evaluated in the local context by the TEC) or on the basis of cost/benefit assessment in the context of user reference)

3. Item should be suitable packed while maintaining the "Cold Chain" throughout transit up until the acceptance from the end user (such as NBC and /or peripheral lab), exactly as recommended/ intended by the manufacturer for each item. Temperatures in particular should be maintained exactly as the manufacturer recommended for each item separately (Proof of manufacturer recommendations on transit conditions should be provided)

4. All reagents intended purpose and limitations declarations, IFUs, worksheets, safety data sheets, quality certificates, brochures, user references and all academic literature supportive of the recommended use and /or comparative advantages, accredited guidelines featuring (E.g., ASHI, BSHI, EFI etc) should be provided, should be in or translated to English language. Academic literature will be evaluated in the context of the quality of publications (Backing of claims by 'larger-scale' met analyses, strength of individual trials, grade of evidence, statistical proofs, appearance in accredited guidance), publication media, evidence of acceptance in wider academia, publications disputing claims by competitive offers etc. by the TEC.

5. If evaluation samples are needed, should be provided within a reasonable time frame (such as 1-2 months of request, as determined by the evaluator), to the address of Director, National Blood Transfusion Services, Colombo -5, for evaluation /re-evaluation and selection. * Statement agreeing to provide evaluation samples in rationalized quantities required by the evaluator if required by the evaluator with terms and conditions should be submitted with the original offer.

6. All items should be eventually delivered to the National Blood Transfusion Service.

7. All assay offers should accompany evidence supportive of (as detailed and extensive as possible) their **comparative merits** (including **comparative advantages in technical characteristics, analysis software characteristics, academic evidence** for the claims) & comprehensive support structure offered (see below). Academic evidence shall be evaluated for standard parameters evaluating such evidence as backing of claims by 'larger-scale' met analysis, strength of individual trials, grade of evidence, statistical proofs, appearance in accredited guidance & industry-wide acceptance by the TEC. Offers will be appraised for the primary assay qualifying for the majority portion procurement & secondary assay qualifying for the minority & overlap portion (for their perceived unique individual merits) of procurement, the ratio of which will be determined by the end-user. (Clinical, Laboratory & administration framework originating the tender)

8. If the need arises, the end-user would reserve the right to individually enhance (independent of each other) either the primary and/or the secondary assay portion procurements, as per the unpredictable nature of reagent consumption, complexities of clinically implementing such comparable, yet uniquely individual assay systems for a single general purpose & cost –benefit dynamics.

9. All offers should accompany, separately be quote & competitively evaluated by the TEC for comprehensive assay application support, specific hardware AND software support & comprehensive continuous capacity building support from technical to clinical application levels in line with global industry standards, **for the total period of usage of the procured assay system quantities by the NBTS.** All offers should have declaration confirming the ability of the end-user to accesses 24hrs & 7 days of local in-person, online global & in-person/in-institution global (within clinically reasonable time frames) application, hardware, software & capacity building support. Technical & capacity building support will be evaluated **at the same level of importance as the assay merits**, while being competitively evaluated for the number, the quantity of events spanning and number of opportunities offered per event. All offers should accompany a list of events & opportunities offered & parameters defining their quality (content delivered and/or experience granted, credentials of presenters, demonstrators and hosts, accreditations, credentials of, global participation & general credentials of participants & historic track-record of delivering such opportunities) & will be critically & competitively evaluated as for **the extremely technical, complex & uniquely proprietary nature of**

   the assays systems, local unavailability of expertise & training resources (as in molecular histocompatibility & immunogenetics, transplant immunology) **& ultimate impact such capacity building had over the years in clinical application of such platforms.**

10. General SOC conditions will also be further subjected & scrutinized according to workflow specific evaluation criteria (criteria for molecular HLA typing stream vs. screening workflow) when required, and will be published with necessary authorization at the time of tendering.

BID NO: DHS/L/WW/102/25 CLOSING ON : 24.02.2025 at 9.00 a.m.

ORDER LIST NUMBER: 2025/SPC/N/C/D/00025

(A) ITEM NO	(B) SR NO	(C) ITEM	(D) QTY	(E) DELIVERY	(F)
1	43604102	MagCore Genomic DNA Whole Blood Kit (Cartrige Code 101) for Automated Nucleic Acid Extractor MagCore HF16 (Model: Compact) Packing : 25 Ext.	1,500 Ext.	750 – Immediately 750 – 6 months after 1st lot	54,044.70
2	43604202	MagCore Genomic DNA Whole Blood Kit (Cartrige Code 102) for Automated Nucleic Acid Extractor MagCore HF16 (Model: Compact) Packing : 25 Ext.	1,200 Ext.	600 – Immediately 600 – 6 months after 1st lot	43,235.76
3	43607802	Manual Whole Blood genomic DNA Extraction Solution /Kit (preferably column-based technology; IVD certification preferred) with all assay specific accessories & consumables (including those for troubleshooting difficult samples, E.g. Proteinase-K, poly-RNase-A etc.) compatible with Luminex xMAP microbead-based rSSOP-PCR +/-second-generation sequencing-based HLA genotyping /sequence-based assays; Solution should preferentially generate dsDNA with preferable purity of A260nm/280nm ~1.7-1.85 (not exceeding or receeding ~1.6-1.95) when measured with UV-absorbance, with minimum length of ~50kbp & at a final elution concentration of not less than ~20ng/?l from a typical sample. Elute should have a minimum salt & RNA contamination. Bid should accompany quality validation certificates demonstrating above parameters (or equivalents) & residual protein, RNA & salt levels together with regulatory certificates (such as IVD) when available. Bid should accompany all protocols & an individual pricing list of all accesories & consumables required (when applicable). Bidder should agree to provide close round-the-clock technical & competency development & troubleshooting support for the period kit usage, which will be critically considered for the subsequent offers. Minimum shelf-life 1year; should specify shelf-life after opening; should quote for all package sizes to be evaluated for efficient usage as per the contemporary usage patter. Bid should describe all storage & handling conditions. (Bid should accompany a typical estimate of accessories & consumables that may be required for the quantity of analyte-specific kits offered) Packing : 25 Ext.	100 Ext.	50 – Immediately 50 – 6 months after 1st lot	

4	43607902	Manual Buccal Swab genomic DNA Extraction Solution /Kit (preferably column-based technology; IVD certification preferred) with all assay specific accessories & consumables (including those for troubleshooting difficult samples, E.g. Proteinase-K, poly-RNase-A etc.) compatible with Luminex xMAP microbead-based rSSOP-PCR +/-second-generation sequencing-based HLA genotyping /sequence-based assays; Solution should preferentially generate dsDNA with preferable purity of A260nm/280nm ~1.7-1.85 (not exceeding or receeding ~1.6-1.95) when measured with UV-absorbance, with minimum length of ~50kbp & at a final elution concentration of not less than ~20ng/?l from a typical sample. Elute should have a minimum salt & RNA contamination. Bid should accompany quality validation certificates demonstrating above parameters (or equivalents) & residual protein, RNA & salt levels together with regulatory certificates (such as IVD) when available. Bid should accompany all protocols & an individual pricing list of all accesories & consumables required (when applicable). Bidder should agree to provide close round-the-clock technical & competency development & troubleshooting support for the period kit usage, which will be critically considered for the subsequent offers. Minimum shelf-life 1year; should specify shelf-life after opening; should quote for all package sizes to be evaluated for efficient usage as per the contemporary usage patter. Bid should describe all storage & handling conditions. (Bid should accompany a typical estimate of accessories & consumables that may be required for the quantity of analyte-specific kits offered) Packing : 25 Ext.	50 Ext.	50 – Immediately	
5	43607903	Buccal DNA collection swab for HLA genotyping applications +/-preservative media Packing : 1 Dev.	200 Dev	200 – Immediately	101,302.32
6	43612201	Salivary genomic DNA Collection Solution /Kit (should be infant & senior friendly & compatible with standard DNA extraction kits & protocols (bid specifically should mention if deviations from a standard protocol of a particular extraction kit is required; compatibility with MagCore DNA extraction technologies are preferred as per the availability of hardware); IVD certification preferred) with all assay specific accessories & consumables (including those for troubleshooting difficult samples, E.g., DNA storage or purification solutions, that could generate ~100 g from a 2ml sample that should be stable storage or transport at ambient room temperature for >1month, with minimal bacterial contamination compatible	100 App	100 – Mar/2025	23,850.00

		with manual column-based DNA extraction technology & Automatic MagCore HF-16 Nucleic Acid Extraction process; extracted DNA should be compatible with Luminex xMAP microbead-based rSSOP-PCR +/-second-generation sequencing-based HLA genotyping /sequence-based assays; Solution should preserve & preferentially generate dsDNA with preferable purity of A260nm/280nm ~1.7-1.85 (not exceeding or receeding ~1.6-1.95) when measured with UV-absorbance, with minimum length of ~50kbp & at a final elution concentration xdcof not less than ~20ng/ l from a typical sample. Elute should have a minimum salt & RNA contamination. Bid should accompany quality validation certificates demonstrating above parameters (or equivalents) together with regulatory certificates (such as IVD) when available. Bid should accompany all protocols & an individual pricing list of all accesories & consumables required (when applicable). Bidder should agree to provide close round-the-clock technical & competency development & troubleshooting support for the period kit usage, which will be critically considered for the subsequent offers. minimum shelf-life 1year; should specify shelf-life after opening; should quote for all package sizes to be evaluated for efficient usage as per the contemporary usage patter. Bid should describe all storage & handling conditions. (Bid should accompany a typical estimate of accessories & consumables that may be required for the quantity of analyte-specific kits offered); Packing : 1 App			
7	43612401	RNase A endoribonuclease solution suitable for genomic DNA purification without DNase activity (E.g., from 'high' absorbance ratio samples) from whole blood, Buccal Swabs, saliva & tissue sources with a reactivity 100 mg/ml OR 7000 units/ml or equivalent (IVD certification preferred but not mandatory) with all assay specific consumables; should be quality validated to be free of DNase. (should be compatible with manual column-based DNA extraction technology +/-Automatic MagCore HF-16 Nucleic Acid Extraction product; extracted DNA should be compatible with Luminex xMAP microbead-based rSSOP-PCR +/-second-generation sequencing-based HLA genotyping /sequence-based assays; Application of solution should preserve & help preferentially generate dsDNA with preferable purity of A260nm/280nm ~1.7-1.85 (not exceeding or receeding ~1.6-1.95) when measured with UV-absorbance, with minimum length of ~50kbp & at a final elution concentration of not less than ~20ng/l from a	34,000IU	34,000 – Immediately	

		typical sample. Elute should have a minimum Protein, salt & RNA contamination. Bid should accompany quality validation certificates demonstrating above parameters (or equivalents) together with regulatory certificates (such as IVD) when available. Bid should accompany all protocols & an individual pricing list of all accesories & consumables required (when applicable). Bidder should agree to provide close round-the-clock technical & competency development & troubleshooting support for the period kit usage, which will be critically considered for the subsequent offers. minimum shelf-life 1year (or equivalent); should specify shelf-life after opening; should quote for all package sizes to be evaluated for efficient usage as per the contemporary usage patter. Bid should describe all storage & handling conditions. Packing : 1IU			

All tenderers should furnish an unconditional Bid Bond for each SR No. encashable on demand to the value mentioned in the Column F.

Amount of Bid Bond should be 2% of the bid value of each item to be submitted along with the bid, **when the tendered value of each item exceeds LKR 01 million. (when not indicated in the Column F).**

Bid Bond should be submitted with valid up to 22.09.2025 together with the tender

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

A non refundable fee of Rs. 12,500/= + taxes should be paid in cash to SPC for each set of Tender Documents and attached it to the Bid.

Note :
Amendments to Global Tender Book,

(I) Clause No 27 (Page 18)
To be deleted 27.4 & 27.5

(II) Clause No 19.1 [REGISTRATION – Page 13]
To be include to read as

(a) For products which are imported to Sri Lanka the registration shall be valid until the last consignment to be procured is received by the Procuring Entity (PE)

(b) For products which are manufactured in Sri Lanka the registration shall be valid until the last delivery of the product to be procured is received by the Procuring Entity (PE)

(III) To replace the clause No 17.4 & 17.5 in contract document on page No 44 to read as above (c) & (d).