

Date: 27-02-25

Tender (Ref: IISc-Med-2024-25/G-13)

GLOBAL TENDER ENQUIRY

To Whom It May Concern

This **Request for Quotation (RFQ)** is for the **planning, supply, installation, testing, commissioning, and training of an Activated Clotting Time (ACT) Measurement System at IISc, Bangalore**. The package should include all necessary accessories and consumables as specified in the tender from **Original Equipment Manufacturers (OEMs)**.

At IISc, the planned infrastructure encompasses a wide array of medical equipment to support advanced imaging capabilities essential for patient care, teaching, and research. The vendors are requested to factor this exposure's value into their quotes. Details of IISc can be gleaned from:

<https://medicine.IISc.ac.in/>

A. Procedure:

1. Vendors are required to submit a technical proposal and a commercial proposal in two separate sealed envelopes. Only vendors who meet the technical requirement will be considered for the commercial negotiation.
2. The deadline for submission of proposals is **March 20, 2025, Thursday, 5:30 pm Indian Standard Time**.
3. Bids in the sealed envelope should arrive at the office of Dean (A & F), Main building, Indian Institute of Science, Bangalore 560012, India, by the above deadline.
4. The technical proposal should contain a technical compliance table with 6 columns.
 - a. The first column must list the technical requirements in the order that they are given in the technical requirement below in tender specifications.
 - b. The second column should provide specifications of the equipment against the requirement (please provide quantitative responses wherever possible.)
 - c. The third column should describe your compliance with a "Yes" or "No" only. Ensure that the entries in column 2 and column 3 are consistent.
 - d. The fourth column should state the reasons/explanations/context for deviations, if any.
 - e. The fifth column can contain additional remarks from the OEM. You can use this opportunity to highlight technical features and qualify the response of previous columns.
 - f. The Sixth column should contain the datasheet & technical offer Page reference number.
 - g. If the required information is not available in the Product Data Sheet and printed technical literature, it must be authenticated by the competent authority of the principal manufacturer, and in case of any discrepancy, the decision of the Technical Committee shall be final and binding on the supplier; additionally, the vendor must provide a legally binding declaration stating that the required information will be demonstrated at the time of handover and commissioning
5. Vendors are encouraged to highlight the advantages of their equipment over comparable equipment from the competitors.

6. In the commercial bid, please provide the itemized cost of the equipment and required accessories, etc.
7. Please provide itemized cost for any suggested/optional accessories/add-on items that may enhance the equipment usability, capability, accuracy or reliability. Vendors are encouraged to quote for as many add-ons as their product portfolio permits.
8. In the quote, you are requested to provide itemized cost for spares, accessories, consumables expected over 2 years of use.
9. Please indicate the warranty provided with the equipment.
10. Any questions or clarifications can be directed to:

Dean (A & F)
Main building, Indian Institute of Science,
Bangalore 560012 tenders@IISc.ac.in

B. Terms and Conditions

1. Only the Original Equipment Manufacturer or their authorized representatives across the globe shall participate in the bid.
2. The order will be placed only on the bidder who participated in the bid.
3. The decision of the purchase committee of IISc will be final.
4. The vendor is responsible for the planning, supply, installation, testing and commissioning of the equipment & the training of personnel of the installed equipment at the IISc.
5. The RFQ must include references to previous installations including the list of all customers where similar systems were installed in the past 5 years. Please provide the names and contact addresses of the referees so that the committee can contact them independently. Details of such systems with model numbers and users should be provided. The reference letters can be used to disqualify vendors with poor track records of service, build quality, system performance, or poor availability of spares.
6. The vendor should have qualified technical service personnel for the equipment based in India and must assure a response time of <2 hours after receiving a service request. The schedule for periodic preventive maintenance for the equipment and all the items related to OEMs should be provided.
7. The indenter reserves the right to withhold placement of the final order and to reject all or any of the quotations and to split up the requirements or relax any or all of the above conditions without assigning any reason.
8. Wherever requested in this specifications sheet, data must be supplied along with technical compliance documents. Technical bids without supporting data will be deemed as technically non-compliant.
9. Upon request, all guaranteed specifications will have to be demonstrated in an active installation. Failure to demonstrate any promised specifications will be deemed as technical non-compliance.
10. Printed literature and published papers to support compliance with the prescribed specifications may be provided duly authenticated by qualified personnel in the company.
11. Technical evaluation by the IISc may include a demonstration to verify the functionalities and capabilities of the equipment quoted. Any discrepancy between the promised and demonstrated specifications will be deemed technical non-compliance. If the need arises, the vendor must be ready to visit IISc for a techno commercial discussion physically.
12. The validity of commercial quotations should be at least 90 days from the last date for the submission of tender documents.

13. **Payment terms:** LC will be opened with 70% payment on shipment of the documents and remaining 20% on installation, testing & commissioning and 10% on user satisfaction. Insurance coverage should be till the commissioning of equipment.
14. The functionalities and capabilities of the equipment to be provided as part of documentation. Any discrepancy in technical specification between what was committed during technical evaluation and demonstrated specification on ground will be deemed technical non-compliance. If the need arises, the vendor must be ready to visit IISc for a techno commercial discussion in person.

C. Other terms

1. Shipment and Delivery Terms

1.1 Partial Shipments

- a. Partial shipments are allowed; however, transshipment is strictly prohibited.

1.2 Delivery Confirmation

- a. Delivery shall only be made after receiving written confirmation from the IISc purchase team.

1.3 Consignee Details

- a. The address of the consignee and the markings on the containers must be clearly stated as per the details provided by IISc.

1.4 Packing Slip and Documentation

- a. A packing slip detailing each item and its quantity shall accompany every shipment.
- b. The packing slip must be securely attached to the exterior of one of the containers in a visible manner.
- c. The purchase order (PO) number must be clearly marked on all packing slips, invoices, and correspondence.

1.5 Missing Items and Substitutions

- a. Any items that are not found upon delivery must be clearly noted on the packing slip, and the anticipated availability of such items shall be indicated.
- b. Substitutions of items shall not be made without prior written authorization from IISc.

1.6 Packing of Fragile Equipment

- a. Fragile equipment shall be packed in wooden boxes to prevent damage during transit.

1.7 Packing of Critical Components

- a. Critical components must be packed using foam/bubble wrap and cartons, and securely stuffed within containers to prevent any damage during transit or handling at the site.

1.8 Protection during Transit

- a. The Seller shall ensure that all items are securely protected and packed in accordance with best established practices to avoid damage under conditions such as multiple handling, transportation by ship/road, storage, and exposure to heat, moisture, rain, etc.

1.9 Seller's responsibility for damage

- a. The Seller shall bear full responsibility for any breakage, damage, or pilferage (including during transit or handling within the hospital) resulting from faulty packing.

1.10 Marking and Packing Slip

- a. All packages must be visibly marked with the purchase order (PO) number and name of the Buyer in bold letters.
- b. Copies of the packing slip must also be placed inside each package.

2. Insurance and Freight

- a. Cost of all Freight & Insurance is Included in the purchase order value will be arranged by the supplier. The insurance should be from the vendor warehouse to the site till Installation & commissioning at IISc.

2.2 Seller Notification for Insurance

- a. If IISc needs to arrange insurance, the Seller must notify promptly.

3. Warranty Terms

3.1 The equipment along with all the 3rd party items should carry a warranty of 12 months from the date of successful commissioning.

3.2 The warranty shall commence from the submission of a duly filled "Medical Equipment Acceptance Sheet Checklist," accompanied by all relevant documents, as per the specifications and requirements.

3.3 After-Sale Service

- a. After-sales service will be provided by a service engineer trained by the principal company.
- b. The credentials and certification of the service engineer shall be shared with IISc for approval.

3.4 Preventive Maintenance and Calibration

- a. Preventive maintenance and calibration shall be performed according to the recommendations of the Original Equipment Manufacturer (OEM).
- b. Preventive maintenance and calibration shall include calibration for any major breakdowns and be conducted in accordance with local rules and regulations, as well as OEM recommendations.
- c. Maintenance and calibration shall also be based on the equipment performance history, using calibrated equipment traceable to international or NABL standards, as required.

3.5 Responsibility for Malfunctions

- a. The seller shall take full responsibility for any mishaps or malfunctions related to the ordered equipment caused by delayed periodic maintenance or calibration under warranty & subsequently in a comprehensive annual maintenance contract.

3.6 Maintenance and Calibration Costs

- a. Preventive maintenance and calibration shall be executed free of cost during the warranty and Annual Maintenance Contract (AMC) period.
- b. The seller shall clearly inform IISc about the list of consumables or maintenance kits that may incur additional costs (not covered under the maintenance contract) before the equipment is supplied.
- c. All accessories, including computer systems, printers, laptops, and software versions, shall be covered free of charge under warranty, rental contracts, and subsequent maintenance agreements.

3.7 Annual Maintenance Contract (AMC) and Comprehensive AMC (CAMC)

The CAMC rate shall be quoted absolute value of the equipment cost per year till nine years post warranty period of equipment. Please refer the template for GENERAL TERMS AND CONDITIONS FOR COMPREHENSIVE/LABOUR MAINTENANCE CONTRACT(CMC/AMC).

3.8 No Additional Terms to be imposed

- a. The seller shall not impose any additional terms on the buyer when an Annual Maintenance Contract (AMC) is established on a yearly basis.
- b. All the terms mentioned in the tender and subsequent purchase order shall remain applicable without any modifications.

3.9 Warranty Terms during CAMC

- a. The warranty terms, including those for preventive maintenance and calibration, shall remain valid and applicable throughout the duration of the CAMC, as per the terms outlined in the tender and subsequent purchase order.

3.10 Payment for AMC and CAMC

- a. Payment for CAMC will be made on a quarterly or annual basis.
- b. Payments will be disbursed upon the successful completion of preventive maintenance and calibration activities, in line with the terms and conditions of the tender and subsequent purchase order.

3.11 Consumables List

- a. The vendor shall provide a list of consumables required for the equipment, along with their associated costs, before the supply of the equipment to IISc.

3.12 Equipment Recall and Standby Equipment

- a. The vendor shall notify IISc of any recall related to the supplied equipment and ensure proper action is taken as per the buyer's recall terms and policies.
- b. In the event of an equipment recall, the seller shall provide suitable standby equipment,

ensuring the clinical functionality of the buyer is not impacted.

3.13 Adverse Event Reporting

- a. Any adverse events associated with the medical devices shall be promptly reported to IISc.
- b. The vendor shall ensure that any adverse event is communicated to the National Collaboration Centre-Materiovigilance Programme of India, in accordance with regulatory requirements.

4. Maintenance and Calibration

4.1 Preventive Maintenance and Calibration

- a. Preventive maintenance and calibration will be conducted free of charge under the warranty period and any subsequent Annual Maintenance Contracts (AMC).
- b. Calibration will be performed in accordance with industry standards and OEM specifications.

4.2 Report of Maintenance and Calibration

- a. The Seller shall provide a report of maintenance and calibration with details of the work performed, including calibration standards and methods.

4.3 Qualification of Engineers

- a. The Seller must ensure the trained engineers are certified and qualified for preventive maintenance and calibration.

5. Spare Parts

5.1 Supply of Spare Parts

- a. The Seller shall supply spare parts for the entire lifetime of the equipment and guarantee availability for a minimum of 10 years from the date of commissioning of equipment.

5.2 Price of Spare Parts

- a. The Seller will provide the prices of major spare parts, which should not exceed 30% of the total equipment value.
- b. A list of critical spare parts and their estimated prices shall be submitted with the tender as part of commercial bid.

5.3 Spare Parts Availability

- a. The Seller must maintain a minimum stock of spare parts to ensure quick availability for repairs.

5.4 Spare Parts Pricing

- a. The prices of spares shall be firm for 5 years, after which adjustments can be negotiated considering inflation and exchange variations.

6. Uptime and Compensation

6.1 Uptime Requirement

- a. The bidder must ensure a minimum uptime of 98% based on a 365-day working year.
- b. In case the uptime falls below the specified 98%, the Warranty/CAMC shall be extended by a ratio of 1:7 days for every additional day of downtime.

6.2 Compensation for Test Failures or Erroneous Results

- a. The seller shall be liable to compensate the buyer for any test failures or erroneous results generated by the ordered equipment.
- b. The compensation amount will be mutually agreed upon by both parties, and this provision will be legally binding.

7. Software and Support Services

7.1 Software Licenses

- a. All software supplied as part of the equipment must come with the necessary licenses for use in India.
- b. The seller shall provide a copy of the software license along with proof of ownership.

The supplied application & operating system software will be kept updated in the form of Free of cost as & when they are released by the factory.

However, for new application software any additional hardware is needed, the cost will be borne by IISc management at negotiated special price.

7.2 Software Support Services

- a. Any software updates or bug-fixing services will be free of charge during the lifetime of equipment.

8. Integration with Clients HIS & PACS-RIS

8.1 Integration Requirement

- a. The Seller must integrate the equipment with clients' Hospital Information System (HIS) & PACS-RIS at no extra cost.

9. Confidentiality and Ownership Transfer

9.1 Confidentiality

- a. The service provider must not acquire or retain any confidential data from IISc.

9.2 Ownership Transfer

- a. Any change in the ownership of the principal company must honour all existing agreements with IISc.

10. Recall of Equipment

10.1 Equipment Recall

- a. In the event of any recall of equipment, the Seller shall promptly inform IISc in writing.
- b. During the period when the equipment is under recall, the Seller shall provide suitable standby equipment of similar or higher specifications to IISc, at no cost.

11. Force Majeure

If either Party is unable to carry out his obligations under this Contract due to an Act of God, war, riot, blockade, strike (I.e. national/ state or city), lockout, flood or earthquake or Government orders/ restrictions not within the control of the parties hereto which results in an Inability, In spite of due diligence of either party in performing its obligation In time, this Contract shall remain effective, but the obligation which the affected party is unable to carry out shall be suspended for a period equal to the duration of the relevant circumstances provided that :

The non-performing party shall give the other Party prior written notice describing particulars of the Inability including but not limited to the nature of occurrence with its expected duration and the steps which the non-performing parties is taking to fulfil its obligation.

Upon receipt of such notice the other party shall discuss the matter with the non-performing party with a view to helping the non-performing party to fulfil obligations. This clause does not envisage financial assistance.

If in any event the Force Majeure situation continues for a period of three weeks both the parties shall meet again and discuss whether the Contract can be amended to overcome the Force Majeure situation so the Project can proceed further.

Notwithstanding anything contained to the contrary it is clarified that economic hardship, non-availability of material, labour and transport shall not constitute Force Majeure. The overall responsibilities and obligations of the parties shall not be excused by reasons of Force Majeure situation.

Notwithstanding the above If the Force Majeure continues for a period of three months or more in that event without prejudice to the rights of the parties, the Buyer shall have the right thereafter to terminate this contract.

12. Seller's Personnel at Buyer's Premises

12.1 Adherence to Safety Regulations

- a. Seller's personnel on IISc premises must adhere to all IISc safety regulations and protocols.

12.2 Seller's Responsibility for Personnel's Safety

- a. The Seller is responsible for their personnel's safety and health while on IISc premises and shall indemnify IISc for any accidents or injuries.

13. Site Evaluation

- a. The Seller must conduct a site evaluation including transportation path, power, air conditioning and other requirements before equipment installation.
- b. The Seller shall submit detailed drawings, specifications, and colour codes for all ordered items for Buyer review and approval via email or other methods. Manufacturing shall commence only after drawing approval and joint inspection of the proposed site.

14. Skilled & trained Engineer for Installation

- a. Installation must be carried out by a skilled engineer and is considered complete only when the equipment is fully operational as per the tender specification.

15. Inspection and Quality Plan

15.1 New Equipment Requirement

- a. Only brand-new equipment will be accepted, and it must be accompanied by quality conformance and manufacturer test certificates.

15.2 Training

- a. Hands-on training for IISc engineers and technicians must be provided at no extra cost.

16. Marketing Support

- a. The Seller shall provide marketing support to IISc as mutually agreed upon.

17. Other terms and conditions

- a. **Software Compatibility** – If the equipment includes software, it must support integration with hospital EMR/HIS via HL7/FHIR standards.
- b. **Standard Accessories** – The system should come with all essential accessories (e.g., power cords, consumables) required for full functionality.
- c. **Regulatory Compliance** – The software should comply with National Health Stack requirements and undergo ABDM sandbox testing, if applicable.
- d. **Data Protection** – Any patient-related data generated by the equipment must adhere to DPDP Act guidelines, if applicable.
- e. **BMS Integration** – The system should include a portal for Building Management System (BMS) integration at no additional cost, if applicable.
- f. **Local Service Support** – Supplier must have a registered office, trained engineers, spare parts, calibration equipment, and installation references in Bangalore.
- g. **Country of Origin Restrictions** – Equipment/materials originating from countries sharing a land border with India will not be accepted.

18. Vendor is to provide compliance with remarks against all terms and conditions

- a. The First column should describe your compliance with a “Yes” or “No” only. Ensure that the

entries in column 1 and column 2 are consistent.

- b. The Second column should state the reasons/explanations/context for deviations, if any.
- c. The Third column can contain additional remarks from the OEM

19. Upon request, a soft copy of the compliance shall be submitted if required for the hard copy submission

TEMPLATE FOR ACCEPTANCE OF MEDICAL EQUIPMENT FOR CLINICAL USAGE

Sr.No.	MEDICAL EQUIPMENT PRE-COMMISSIONING CHECK-LIST	Vendor to fill the details
1	Equipment name	
2	Main Unit Model & Serial No	
3	Date of receipt of equipment at site	
4	Goods opening report (item wise)	
5	Principal Company name	
6	Dealer/ Vendor name	
7	Vendor contact details including email address	
8	Equipment Model name	
9	User Department name	
10	End User (Head of Dept) Signature	
11	Clinical Engineers name	
12	Clinical Engineers Signature	
13	Service Engineers name and Contact number	
14	Application specialist name and contact number	
15	Main Unit - hardware as per Purchase Order (Vendor-signed PO and list of items supplied as per PO with invoice) to be enclosed as part of the commissioning documentation.	
16	Main Unit - software as per Purchase Order (Vendor-signed PO and list of software supplied as per PO with invoice) to be enclosed as part of the commissioning documentation.	
17	OEM items as per Purchase Order (Vendor-signed PO and list of items supplied as per PO with invoice) to be enclosed as part of the commissioning documentation.	
18	Accessories as per Purchase Order (Vendor-signed PO and list of items supplied as per PO with invoice) to be enclosed as part of the commissioning documentation.	
19	Consumables as per Purchase order- (Vendor signed PO and List of items supplied as per PO with invoiced) to be enclosed as part of commissioning documentation	
20	Brochure of equipment to be enclosed as part of the commissioning documentation.	
21	Technical Data Sheet to be enclosed as part of the commissioning documentation.	

22	Set of service manuals (1 hard copy & 1 PDF soft copy) to be handed over to the Clinical Engineering Dept.	
23	Set of instruction manuals - Two copies (1 hard copy and 1 PDF) to be handed over to the Clinical Engineering Dept.	
24	List of spares & additional accessories with re-ordering codes and costs used along with the equipment as a standard package (PDF).	
25	Equipment demo training information materials like PPT/Video to be handed over to the Clinical Engineering department.	
26	Duly signed letter from the vendor organization head (MD/CEO) stating that the supplied unit, accessories & OEM items are brand new from the factory, to be enclosed as part of the commissioning documentation.	
27	Quality test certificate of equipment from the factory, duly signed by the factory production in-charge, to be enclosed as part of the commissioning documentation.	
28	Software license document (PDF); including OS, system and application software, and commitment to support over the lifetime of the equipment, to be enclosed as part of the commissioning documentation.	
29	All cables from the equipment should have proper cable management, i.e., cable labeling.	
30	2S and HIRA (Hazard Identification and Risk Assessment) to be conducted during preventive maintenance wherever applicable to keep the working area clean.	
31	First-level training to Clinical Engineering (training certificate).	
32	Application training to the end-user on all functions demonstrated (training certificate).	
33	Do's and Don'ts for the equipment for the user group to be provided as part of the training module, to be enclosed as part of the commissioning documentation.	
34	Preventive maintenance frequency calculated based on Equipment Risk Classification, Usage and Operational Intensity, Manufacturer's Recommendations, Historical Performance, and Failure Data.	
35	Preventive maintenance (PM) checklist to be predefined & duly filled during preventive maintenance, to be enclosed as part of the commissioning documentation.	
36	Preventive maintenance kit specification & details to be shared in advance, to be enclosed as part of the commissioning documentation.	
37	Preventive maintenance schedule should be done during non-clinical work operational hours based on prior approval from the user.	
38	Calibration schedules should be based on Manufacturer's Recommendations and after every major equipment breakdown servicing.	
39	The calibration process should follow NABL 126 guidelines.	
40	With each maintenance work, the service provider should hand over two physical copies of the service report (one for the user and one for the Clinical Engineering Dept.) along with a duly filled PM checklist. If physical copies are not available, soft copies should be provided to both the user	

	and the Clinical Engineering Dept. Accepted downtime in hours & accepted equipment breakdown frequency as per PO terms should be understood by the service team, including downtime penalty	
41	Accepted Downtime in hours & accepted equipment breakdown frequency as per PO terms are understood by service team including downtime time penalty.	
42	The service provider should maintain a logbook of maintenance at the user site.	
43	Shelf-life details of critical spares/accessories/consumables to be provided, to be enclosed as part of the commissioning documentation.	
44	Commissioning report should include (IQ/PQ/OQ) as part of equipment commissioning documents, duly signed by the user group, to be enclosed as part of the commissioning documentation.	
45	Cleaning & disinfection methodology, including the material used, to be provided at the time of commissioning of equipment, to be enclosed as part of the commissioning documentation.	
46	User application training schedule to be provided along with the PM schedule.	
47	Training materials soft copy (PPT/Video) to be shared for installation sign-off.	
48	Letter from the principal manufacturer stating their commitment to IISc for support of equipment for the coming years as per Purchase Order terms to be provided.	
49	CE/FDA, CDSCO Certificate to be enclosed as part of the commissioning documentation.	
50	The single-phase power cord supplied along with the equipment should have a 3-pin plug (Neutral, Phase, Earth) for Indian usage.	
51	Warranty card and details of the warranty to be enclosed as part of the commissioning documentation.	
52	Short shipped items (if any) with quantity. The warranty will start only after full supply, installation, testing, and commissioning of hardware, application software, and third-party equipment supplied along with the main equipment.	
53	OEM and Dealer Sales and Service Escalation contact details, including CEO/MD, to be enclosed as part of the commissioning documentation.	
54	Life of the equipment as committed during technical discussions to be provided with maintenance and spare support during the course of the year, irrespective of dealer change, as per PO terms and conditions, to be given on the OEM letterhead. In case the OEM stops service support during the sales-committed life, the vendor is expected to compensate with the depreciated cost of equipment or provide buyback or upgrade options according to the hospital's requirements.	
55	Any adverse events and recalls related to the equipment, if reported, need to be intimated to IMSF in a timely manner to ensure patient & staff safety by the vendor.	

	Signature: User Dept Head Head-Clinical Engineering	
	Date and Time	
	All these details should be given in a spiral bound document by vendor to IISc.	
	EQUIPMENT WARRANTY WILL START ONLY AFTER FULL COMPLIANCE OF ABOVE FORM	

GENERAL TERMS AND CONDITIONS FOR COMPREHENSIVE/LABOUR MAINTENANCE CONTRACT(CMC/AMC)	
1)	ALL TERMS AND CONDITIONS REMAIN UNCHANGED AS PER SALES PO
2)	AMC & CMC VALID FROM _____ TO _____
3)	THIS CONTRACT INCLUDES
1	All equipment and items supplied by the OEM are covered under service contracts and must be replaced free of cost under CMC.
2	All equipment must be serviced by trained, authorized service engineers. The training certificate of the engineer must be submitted to the IMSF Clinical Engineering Team in advance.
3	Preventive maintenance frequency is calculated based on equipment risk classification, usage, operational intensity, manufacturer's recommendations, historical performance, and failure data.
4	The equipment preventive maintenance must be performed according to the predefined checklist provided in the service manual.
5	Operating system and anti-virus updates are an integral part of preventive maintenance.
6	The vendor will not allow their service engineer to train junior staff on our equipment.
7	Vendor to attend unlimited breakdown calls.
8	Call response time of two hours to be maintained; response time to attend calls within 2 hours is applicable, including holidays and non-working hours.
9	Breakdown frequency should not exceed twice the frequency of preventive maintenance.
10	Vendor must submit soft copies of all reports in two copies.
11	Vendor must maintain a service logbook at the user department.
12	Yearly downtime and breakdown frequency will be calculated based on the call logbook.
13	Any damage to hospital property during maintenance by the company engineer should be compensated to the hospital.
14	Vendor must ensure two preventive maintenance visits per year before the due date. Any malfunction or harm to the patient due to delayed preventive maintenance or calibration will be the sole responsibility of the vendor, including legal compensation. Preventive maintenance and

	calibration must be mandatory after repair or replacement of any spare parts, and necessary kits are to be provided FOC.
15	A copy of the preventive maintenance report with a checklist and a soft copy of calibration, if applicable, is to be shared within one day of execution. The preventive maintenance and calibration label, with done and due dates, must be affixed to the machine without fail, along with the clinical engineer.
16	Periodic training to clinical engineers and end-users, as and when applicable, is mandatory. Training documents must be provided for all concerned staff prior to the renewal of the contract. It is the vendor's responsibility to ensure training, including application training for all staff, without fail. Training materials (PPT/Video) must be submitted to the clinical engineering team prior to any training.
17	Vendor should provide the cleaning and disinfection protocol for the equipment, carry out necessary training periodically, and ensure that all concerned members are trained on the same.
18	Any recall related to the above equipment must be notified in writing, and required corrective actions must be carried out FOC. Necessary training must be provided to concerned staff.
19	Any adverse event reported must be intimated to the Materiovigilance department, and corrective action must be shared within one working day with the hospital.
20	Complete breakdown details, including downtime and preventive maintenance/calibration history, must be shared before the renewal of the next contract. Any downtime of more than 48 hours must include root cause analysis and corrective & preventive action with due diligence. Service reports must be legible and include call received, call attended, and call closed (including date & time) accurately. Any report missing this information will be deemed incomplete.
21	Unlimited spare support must be provided, except for consumables (filters). All accessories and parts are covered and included in the contract. Spares must be ordered and moved immediately after diagnosis, including during holidays and non-working hours.
22	Uptime must be maintained at 98%, including holidays and non-working hours.
23	Uptime is defined by the machine working for its intended purpose without compromising patient care or revenue. Any deviation will count as downtime, and for any additional downtime, the contract will be extended by 1:7 days.
24	A maximum of two breakdowns per preventive maintenance frequency is permitted. Any deviation will increase the preventive maintenance frequency in the subsequent year with any cost escalation.
25	Standby equipment must be provided within a day if the issue cannot be resolved for movable equipment.
26	The vendor escalation matrix, including sales and service contact details (mobile numbers & email IDs), must be provided without fail.
27	First-level service training must be provided for the concerned equipment, and the training certificate must be provided to the clinical engineering team members.
28	Preventive maintenance must not be executed during peak working hours and must be carried out as per the user's convenience. The preventive maintenance kit is included in the CMC and must be replaced during preventive maintenance.

29	The AMC bill will only be cleared after the submission of the equipment log report, which must include details of downtime and preventive maintenance (PM) or calibration history. This report must be provided prior to the renewal of the contract.
30	For equipment under AMC, the quotation for spare parts must be provided within one day of the service engineer's recommendation in the service report.
31	For equipment under AMC, no cannibalization of spare parts from working equipment by the service engineer is allowed.
32	Any spare part ordered for equipment under CMC must reach the hospital site within 72 hours.
33	If the equipment remains non-functional after spare part installation, the concerned service engineer must be replaced from the IMSF site.
34	All defective spare parts under AMC will be retained by the hospital. For equipment under CAMC, IMSF will mark the spare part as defective, and a non-returnable gate pass will be issued.

Template for purchase order terms	
General: Acceptance of this Purchase/ Work Order (hereinafter referred to as "PO/Order") includes the acceptance of the following terms & conditions and is made expressly conditional on Seller's assent to the exact terms contained herein. None of the terms in the Order may be modified, added to, or superseded, except with the written consent of Indian Institute of Science ("Buyer").	
1.Price: The prices mentioned in this Order are the prices at which Buyer has agreed to purchase the Goods or Services (as applicable). No escalation in the aforesaid prices shall be binding on Buyer, notwithstanding anything that may be mentioned in Seller's terms of acceptance of Order.	
2.Advice of Dispatch: A full and comprehensive dispatch advice notice shall be sent to stores or concerned departments of the Buyer ("Buyer Stores"). Instructions regarding dispatch & Insurance as mentioned in this Order should be complied with and the packing slips giving reference of Buyer order number shall be included securely with the goods in closed envelopes.	
3.Delivery Terms: (a) Deliver Date: Time is the essence in any Purchase Contract. Time of delivery/performance as mentioned in this Order shall be the essence of the Agreement and no variations shall be permitted except with prior authorization in writing from the Buyer. (b) Place of Delivery: The goods/services shall be delivered/performed strictly as per the instructions in the Order. All Goods/Services delivered/performed at should reach Buyer Stores before 2.00 p.m. on weekdays except that no deliveries/ dispatches shall be made or accepted on Sundays or holidays in the working place of the Buyer. (c) Delayed Delivery: The time and date of delivery/performance as stipulated in the Order shall be deemed to be the essence of the Agreement. In case of delay in performance of its obligations by the Seller, or any extension granted by the Buyer, the Buyer shall at his option either (i) accept delayed deliveries at price reduced by a sum/ percentage (%) mentioned in the Purchase Order for every week of delay or part thereof; and/or (ii) cancel the Order in part or in full and purchase such cancelled quantities from open market at the prevailing market price at the risk & cost of the Seller without prejudice to his rights under 3(c) (i) noted above in respect to the goods delivered; and/or (iii) refuse to accept the Goods delivered beyond the delivery date and claim/set-off the difference between the prevailing market price and contracted price of such quantity delivered belatedly by the Seller.	

(d) Delay due to force majeure: In the event of cause of force majeure occurring within the agreed delivery terms, the delivery date may be extended by the Buyer at its sole and absolute discretion on receipt of application from the Seller without imposition of liquidated damages. Only those cause which have duration of more than seven (7) consecutive calendar days will be considered the cause of force majeure. The Seller must inform the Buyer, by a Registered Post or courier letter duly Certified by the Chamber of Commerce or Statutory Authorities, the beginning and the end of the cause of delay immediately, but in no case later than ten (10) days from the beginning and end of each cause of force majeure as defined above.

(e) The goods shall correspond with the description of the samples of the original specification thereof in full details and must be delivered and dispatched within the stipulated time, as the case may be. Otherwise, the same shall be liable to be rejected and the Seller shall be deemed to have failed to deliver the goods in breach of the PO. The Buyer shall in that event at its sole and absolute discretion, will be entitled to either purchase such goods from other sources on Seller's account, in which case, the Seller shall be liable to pay to the Buyer any difference between the price at which such goods have been purchased and the price calculated at the rate set out in this Order or to hold the Seller liable to pay the Buyer damages for non-delivery of goods for such breach.

(f) Packing: Goods supplied against this order must be suitably and properly packed (conforming to special conditions stipulated by the Buyer, if any, for safe and/or undamaged transport by road or rail.)

4. Examination of goods: Irrespective of the fact that the goods are delivered to the Buyer by the Seller at the Seller's place or at Buyer's said office or are dispatched as per Buyer's instructions by rail or road, the goods shall always be supplied, subject to detailed inspection, at the Buyer works or such other destinations as specified in the Order for ascertaining whether the goods are in conformity with the Agreement or not and until then in no event the Buyer shall be deemed to have accepted such goods and upon any rejection of goods in question the Seller shall be deemed to have failed to deliver the concerned goods in accordance with the Agreement.

5. Rejection/ Removal of rejected goods and replacement: Buyer shall have the right to reject the goods whether in full or parts which are not delivered in accordance with the terms of the PO. within fifteen days from the receipt of the intimation from the Buyer of his rejection to accept the goods the Seller shall remove, at his own cost, the rejected goods from the Buyer's works or wherever such goods are lying. The Buyer shall not be in any way responsible for or be held liable for any loss or deterioration of the rejected goods as this shall be at the Seller's risk entirely. The Seller shall pay to the Buyer reasonable storage charges for storing such rejected goods for a period exceeding 15 days as aforesaid. Upon rejection, if the Seller fails to replace the goods with the goods acceptable to the Buyer within the contractual period then the Buyer may, solely at his discretion, exercise all or any of the following options in respect of the rejected/undelivered quantity:- a. Dispose-off the rejected goods and claim/set-off the difference between the prevailing market price and contracted price of such undelivered/rejected quantity to the Seller's account; and/or b. purchase such undelivered/rejected quantity from the open market at the prevailing market price at the risk and cost of the Seller.

6. Transit Insurance: In case insurance is not included in Seller's scope he must furnish details such as reference, Lorry Receipt, Note No., nature of packing, number of cases, gross weight net weight, train carrying the goods, value of the goods dispatched etc. immediately on dispatch to Buyer's office to take up insurance in case of goods sent by Regd... Post, the Regd. Post parcel No. should be furnished to the Buyer with a packing slip when action will be taken to insure the goods. This procedure will be adopted unless specially advised by the Buyer to the contrary.

7. Insurance: Seller agrees that during the term of its performance hereunder, it shall, at its sole cost, maintain worker's compensation insurance and other legally required insurance in accordance with and meeting requirements of applicable law.

8. Invoices: All bills/ invoices for supplies/ services made bearing registration number of the Seller should be marked to concerned Office or as mentioned in Order (quadruplicate) duly endorsed with Purchase Order, Reference Number and Date and be accompanied by advice of dispatch detailed packing list and by an appropriate certificate necessary under the GST Registration Rules and Regulations.

9. Billing Instructions: Seller must follow the billing instructions carefully and correctly to enable early settlement of his dues. Disregarding the same may involve delay in such settlement. Seller must mention the following information in his bill: (1) Vendor Code Number (2) Purchase Order Item Number (3) Material Code Number, if any. The abovementioned information will be always available in this Order sent to him. One copy of the above document is to be sent to Buyer at The Assistant Registrar, Stores and Purchase Section, Indian Institute of Science, Sir C V Raman Avenue, Bengaluru-560012 or to the address as advised by the Buyer.

10. Compliance with laws: It is clearly reiterated that the Seller is representing an Entity which is strictly complying with all the Laws of the Land as is expected generally from a Seller of a product. It is also made explicitly clear that (a) the Seller has and shall maintain as valid shall under this order strictly comply with the specifications and the requirements agreed upon. At any given point of time, the seller is obliged to produce all applicable licenses, permits, approvals, authorizations and/or or other statutory approvals required to perform its obligation/s under the PO; (b) shall at all times duly observe, perform and comply with all obligations, requirements and/ or prohibitions contained in any statutes, regulations or ordinance of any authority whether governmental or provincial, relating to or in any way affecting or regulating the respective performance of the PO by it.

11. Standard GST Clause: a. The price quoted in this PO for supply of goods shall be exclusive of any applicable Goods and Services Tax, Customs duties, or any other indirect tax as may be imposed by the Government of India from time to time. The Seller shall provide a proper invoice in the form and manner prescribed under GST Invoice Rules containing all the particulars mentioned therein. In the event that the Seller fails to provide the invoice in the form and manner prescribed under rules, Buyer shall not be liable to make any payment against such invoice. Notwithstanding anything contained anywhere in the Agreement, in the event that the input tax credit of the GST charged by Seller is denied by the tax authorities to Buyer, Buyer shall be entitled to recover such amount from the Seller by way of adjustment from the next invoice. In addition to the amount of GST, Buyer shall also be entitled to recover interest at the applicable rate and penalty, in case any penalty is imposed by the tax authorities on Buyer. b. As required by any applicable legislation, where identifiable cost savings are realised by virtue of the enactment of the GST law, those cost savings will be reflected in the calculations of the consideration under this Agreement and shall be passed on by the Seller to Buyer. c. Event of default clause – In the event that the Seller does not deposit the GST charged on the invoice issued to Buyer or such GST charged on the invoice and paid by Buyer is not reflected in online tax credit ledger on common GSTN portal of the govt. as eligible input tax credit for any reason whatsoever, this Agreement shall be liable to be terminated with immediate effect and Seller shall be liable to pay such damages as may be reasonably estimated by Buyer. In the event that the compliance rating prescribed under the GST Act, 2017 read with GST Rules, 2017 of Seller falls below prescribed level for any reason whatsoever, this Agreement shall be liable to be terminated with immediate effect and Seller shall be liable to pay such damages as may be reasonably estimated by Buyer. d. Representation and warranties clause – The Seller represents and warrants that it shall have and maintain in effect level of compliance rating as prescribed by the govt.

12. Warranty: The Seller warrants that goods and/or services supplier shall be of the highest grade and quality unless otherwise specified; shall conform to the specifications, drawings, samples or other descriptions contained in the Order or furnished or specified by the Buyer; shall be performed in a workmanlike manner; shall be fit and sufficient for the purpose intended; shall not violate any third party intellectual property rights and shall be merchantable, of good material and workmanship and free from all the defects whether latent or patent. In case the same is found to be defective, inter-alia, in respect of materials, workmanship, design or process of manufacturing within a period 12 months after the same had been put in use or 20 months from the date of acceptance of the goods by the Buyer, whichever is earlier, the Seller shall refund the price paid by the Buyer in respect of the said goods. The Seller shall guarantee that the material Seller further agrees that all materials / goods shall be repaired or replaced as the case may be as noted in Clause 20 below. All spare parts should carry the following: a) Name of the Machine b) OEM/Party's name c) Sr. at his / her own expense. The Seller shall be liable for all costs and damages and replacements at the sole option of the Buyer. These warranties are in addition to those implied by or available at law to Purchaser and shall exist notwithstanding the

acceptance and/or inspection by Purchaser of all or part of the goods or services.
13. Right of the Buyer to Set Off: In the event, the Seller fails to deliver the goods in accordance with the terms of this PO, the Buyer shall have the right to cancel the PO forthwith and claim refund of any payment made by the Buyer as advance or otherwise to the Seller under the PO. The Buyer shall also have the absolute right to withhold, adjust, and/ or set-off any payment required to be made by the Buyer to the Seller under this PO or any other PO entered into between the parties against the cost, losses, damages etc. suffered by the Buyer due to the failure of the Seller to deliver the Goods in accordance with the terms of this PO, and the Seller expressly waives any objections it may have in this respect.
14. Cancellation/Termination: The Buyer reserves the right to cancel/terminate this Purchase Order or any part thereof. The Buyer shall be entitled to rescind the Agreement wholly or in part in a written notice to the Seller if (i) The Seller fails to comply with the terms of the Purchase Order; or (ii) The Seller goes bankrupt or goes into liquidation proceedings; or (iii) The Seller fails to deliver the goods on time and / or replace the rejected goods promptly; or (iv) the Seller fails to deliver the Goods/Services of desired quality, weight, specification, drawing, layout, design, etc.; or (v) The Seller makes general assignment for the benefit of the creditors; or (vi) Receiver is appointed in respect of property of the Seller. The Buyer shall also be entitled to cancel this Order without assigning any reasons or becoming any way liable in such cancellation.
15. No Assignment: This Purchase Order shall not be assigned to any other agency by the Seller without obtaining prior written consent of the Buyer.
16. Force Majeure: Failure or omission to carry out or observe any of the stipulation or condition of the Agreement shall not give rise to any claim or be deemed a breach of the Agreement if the same shall arise from any of the following causes. viz. the imposition or restriction on Import, Acts of God. The Seller submits his acceptance of this agreement with the above conditions by acceptance of Buyer's Order even in cases where the confirmation has been made under assumption of different conditions.
17. Special Conditions: Seller will ensure that all statutes, regulations of the Central or State Government are strictly followed. Buyer shall not be liable to pay any damages/compensation due to non-compliance of these rules / regulations by Seller.
18. Arbitration: Any dispute arising out of or in connection with the agreement shall be settled by Arbitration in accordance with the Arbitration Conciliation Act, 1996. The arbitration proceedings shall be conducted in English in Bengaluru by the sole arbitrator appointed by the Buyer. The cost of arbitration shall be shared equally between the parties unless decided otherwise by the arbitrator.
19. Dispute & Jurisdiction of Bengaluru: All disputes shall be subjected to the exclusive jurisdiction of the court in Bengaluru only or as provided in the PO/Order.
20. Limitation of Liability: In no event shall Buyer be liable to Seller, or to Seller's officers, employees or representatives, or to any third party, for any indirect, consequential, incidental, special, punitive or exemplary damages of whatsoever nature (including, but not limited to, lost business, lost profits, damage to goodwill or reputation and/or degradation in value of brands, trademarks or trade names, service names or service marks, or injury to persons) whether arising out of breach of contract, warranty, tort (including negligence, failure to warn or strict liability), contribution, indemnity, subrogation or otherwise.
21. All spare parts should carry the following: a) Name of the equipment b) OEM/Party's name c) Sr. No. as per the catalogue d) Buyer's Order No. and date and e) Quantity all relevant information.
22. Works carried out in Buyer's Institution or premises by the Sellers representatives etc.: Agent representative or employees of the Seller who in pursuance of the Agreement have to work in Buyer/Owner's Institution/Premises will be subject to the rules and regulations existing in the works. The Buyer shall not be liable for any accident which may cause to the Sellers personnel.
23. Intellectual Property Rights: All drawings, specifications and other documents furnished by Buyer

and the Buyer's consultants, and copies thereof furnished to the Seller, are for use solely with respect to this Order. Such drawings, specifications and other documents are to be returned to the Buyer at the completion of the Order or earlier termination of this Agreement. All drawings, specifications and other documents prepared by or for Seller in contemplation of, in the course of, or as a result of performing the work shall be deemed works for hire and all right, title and interest therein shall vest in Buyer, whether or not the Order is ultimately completed. To the extent such drawings, specifications or other documents cannot be considered, by operation of law, works for hire, Seller shall assign to Buyer all right, title and interest thereto and all copies of such drawings, specifications and other documents shall be delivered to Buyer upon completion of the Order or earlier termination of this Agreement. Seller agrees to provide Buyer with reasonable assistance necessary to perfect Seller's interest in intellectual property created under this Agreement. This shall include, but not be limited to, the execution of documents necessary for the Copyright registration. No drawings, specifications or other documents may be used by the Seller or any Sub seller or material or equipment supplier on other projects or for additions to their Project outside the scope of the work without the specific written consent of the Buyer. The Seller, Sub suppliers, Sub-Sub suppliers and material or equipment suppliers are authorized to use and reproduce applicable portions of the drawings, specifications or other documents appropriate to and for use in the execution of their work under the contract documents. All copies made under this authorization shall bear the statutory copyright notice, if any, shown on the drawings, specifications and other documents prepared by or for the Buyer. Submittal or distribution to meet official regulatory requirements or for other purposes in connection with this Project is not to be construed as publication in derogation of the Purchaser's copyrights or other reserved rights. Any intellectual property conceived or developed during the course of the Order based upon or arising from Buyer's confidential and proprietary information shall be solely owned by Buyer. Except as expressly provided herein, no license or right is granted hereby to the Seller, by implication or otherwise, with respect to or under any patent application, patent, claims or patent or proprietary rights of Buyer.

24. The terms and conditions of this Order constitute the entire Agreement between the parties here to and changes will be binding only if the amendments are made in writing and signed by the authorized representatives of the Buyer and the Seller.

25. Risk of loss and/or damage to any goods furnished hereunder shall be upon Seller until the goods are physically delivered to Buyer's facility specified on the face of the Order and accepted by the Buyer.

26. Indemnification: Seller agrees to defend, indemnify and hold harmless the Buyer, its affiliated companies or parent companies, and their officers, employees, agents, guests, invitees and customers from and against any and all liability, loss, damage, fine, penalty, cost or expense (including attorneys' fees) by reason of any allegation, claim, action or suit, whether for death, personal injury, property damage or otherwise, arising out of (1) failure of the goods or services supplied to meet specifications or warranties or for the goods or services to be otherwise defective; or (2) any alleged or actual, direct or contributory infringement or misappropriation of any patent, copyright, trade secret or other proprietary right arising from the purchase, use or sale of such goods or services; or (3) any leak or spill of any goods while being transported or delivered to Buyer; or (4) any breach by Seller of any term or condition contained in the Order; or (5) violation of applicable laws; or (6) alleged defect in the Goods and/or packaging material, or packed Product, or due to the Goods or packaging thereof being alleged to not adhere to any standard or quality set out herein or under any applicable laws; and/or (7) the acts, omissions, or wilful misconduct of Seller's employees and subcontractors, including their agents and representatives, and all other persons performing any services under the Order with the Seller, whether or not caused in part by a party indemnified hereunder. In the event that the goods or services, in Purchaser's reasonable opinion, are likely to infringe a patent or copyright, or misappropriate a trade secret (and in any event, if a court of law finds that the goods or services, in fact, do infringe or misappropriate), then Seller shall further provide Buyer one of the following forms of relief to be chosen by Seller: (a) obtain a license on Buyer's behalf to continue to use or sell the goods or services; (b) redesign the goods or services so that they do not infringe or misappropriate; or (c) refund Buyer the price paid for the goods or services in question. In any and all claims against Buyer by any employee of Seller, any subcontractor, anyone directly or indirectly employed by any of them, or anyone for whose acts any of them may be liable, the indemnification obligation under the Paragraph shall not be limited

in any way by any indemnity or limitation on the amount or type of damages, compensation or benefits payable by or for Supplier, any subcontractor, or anyone directly or indirectly employed by any of them under workers' compensation acts, disability benefit acts, or other employee benefit acts.

27. Confidentiality: Seller shall keep confidential all specifications and proprietary information furnished by Buyer or prepared by Seller in connection with the performance of the Order (including the existence and terms of the Order) and shall not divulge or use such specifications or information for the benefit of itself or any other party, except as required for the efficient performance of the Order. Upon completion of the Order, Supplier shall make no further use, either directly or indirectly, of any such specifications or information.

28. Disposal: If applicable, Seller shall at all times retain title of ownership to any and all materials, substances or chemicals not incorporated into the work that Seller or any subcontractor brings onto Buyer's premises. Seller shall be solely responsible for the handling, transportation and disposal of any and all materials, substances and chemicals. Seller or any subcontractor brings onto Buyer's premises, and any waste generated or resulting from the use thereof. Seller shall not dispose or permit the release of any materials, substance or chemical, or any waste generated or resulting from the use thereof on Buyer's premises. Seller shall handle, transport, and dispose of any and all substances and chemicals, including but not limited to hazardous wastes and substances as defined by applicable federal, state and local laws, rules, regulations, codes and ordinances.

29. Severability: If any provision of this Agreement is held to be invalid, illegal or un-enforceable, either in whole or in part, that holding will not affect the validity, legality or enforceability of the remaining provisions of this Order

30. Original Excise Gate pass must accompany each delivery for excisable goods, if applicable.

31. The Seller will not claim without our knowledge any refund from the excise authorities for the amount of Central Excise duty on the supplies made to us. The Seller shall also undertake to refund to the Buyer all money recovered by him from Govt. authorities for which he has been paid by the Buyer.

32. Unless a specific objection to each of the terms of this Purchase order is raised within 24 hours from the date of Purchase order/email under which this PO is sent, it shall be deemed to be accepted in full.

33. Supplier (Seller) Code of Integrity: The Seller/ Supplier agrees to follow code of integrity and code of conduct as prescribed by General Financial Rules 2017.

TENDER SPECIFICATION

SN	Specification	Details
1	Function	The system shall be designed for the measurement and assessment of Activated Clotting Time (ACT) in clinical settings.
2	Portability	The machine shall be compact and portable for bedside testing.
3	Heating Mechanism	The system shall have an inbuilt mechanism to heat the cartridge.
4	Temperature Range	The operating temperature shall be $37.0 \pm 2^{\circ}\text{C}$.
5	Sample Volume	The machine shall require less than 2ml of blood for each test.
6	Report Display	The system shall be capable of displaying two reports simultaneously.
7	Cartridge Supply	The package shall include 100 cartridges for each test.
8	Measurement	The ACT machine shall have a measurement range of 0-1500

	Range	seconds.
9	Display	The system shall have an LED/LCD-based fully digital display screen.
10	Operating Environment	The machine shall operate within a temperature range of 15°C - 30°C.
11	Data Transfer	The system shall support data transfer with a printer option and the capability to store and view multiple patient records.
12	User Interface	The machine shall have a one-button operation for ease of use.
13	Regulatory Approvals	The system shall be US FDA / European CE approved.
14	System Control	The machine shall be microprocessor-controlled to determine coagulation endpoints in whole blood, citrated blood, and plasma samples.
15	Testing Method	Please specify if dual well testing method is available or not
16	Tube Compatibility	The vendor shall specify the compatibility of the system with Actalyte ACT tubes with celite, glass bead activator, MAX ACT tubes with blended activator, and all international Technidyne Hemochron tubes.
17	Consumables	The seller shall provide a list of consumables with prices frozen for five years.
18	Battery Backup	Please specify if system have a battery backup of at least 2 hours.
19	Desirable Features	The system shall support Rate of Actual Clot Formation (CR, Clot Rate: Thrombin Activity, Low Molecular Weight Heparin Management).
20	Other Terms	
20.1	The seller shall provide a separate list of all available optional hardware, accessories, and consumables from their catalog, along with unit costs	
20.2	The system should have US FDA/ European CE certified with 4-digit notified body number, ISO, CDSCO	