Ref. No.: F.02(173)/RMSCL/LAB EMPANELMENT(S&S)/NIB-10/2024/3622 Dated:- 12.06.2024

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
(A Govt. of Rajasthan Undertaking)
Gandhi Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India
Tel No: 0141-2228066, 2228064, E-mail: edpssrmsc@rajasthan.gov.in

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF SURGICAL & SUTURES / MEDICAL DEVICES (30.09.2026)

!! सर्वे सन्तु निरामयाः!!

LAST DATE OF SUBMISSION OF ONLINE BIDS	**09.07.2024 at 6.00 PM**
DATE AND TIME OF OPENING OF ONLINE TECHNICAL BIDS	**10.07.2024 at 11.00 AM**

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
(A Govt. of Rajasthan Undertaking)
Gandhi Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India
Phone No: 0141-2228066,2228064 Website: www.rmsc.health.rajasthan.gov.in
CIN:U24232RJ2011SGC035067 E-mail : edpssrmsc@rajasthan.gov.in

Ref : F.02(173)/RMSCL/LAB EMPANELMENT(S&S)/NIB-10/2024/3622 Dated:- 12.06.2024

Notice Inviting E-Bids

E-Bid for the Empanelment of Analytical Testing laboratories For the Test and Analysis of Surgical & Sutures/Medical Devices are invited from the eligible bidders :-

S. No	Item Name /Description	Ref. No	Estimated cost	UBN	Last Date Of Submission Of Online Bids
1	E-Bid For The Empanelment Of Analytical Testing laboratories For The Test And Analysis Of Surgical & Sutures/Medical Devices	F.02(173)/RMSCL/LAB EMPANELMENT(S&S)/NIB-10/2024/3622 Dated:- 12.06.2024	40.98 Lakhs		09.07.2024 up to 6.00 PM

Other particulars of the bids may be visited on the procurement portal http://eproc.rajasthan.gov.in, http://sppp.rajasthan.gov.in and www.rmsc.health.rajasthan.gov.in and may be downloaded from there.

Executive Director (Procurement)
RMSCL

RAJASTHAN MEDICAL SERVICES CORPORATION LTD. RAJASTHAN

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF SURGICAL & SUTURES/MEDICAL DEVICES (Ending on 30.09.2026)

Bid Reference	:	**Ref. No.:** F.02(173)/RMSCL/LAB EMPANELMENT(S&S)/NIB-10/2024/3622 Dated:- 12.06.2024
Date and time for downloading bid document	:	13.06.2024 from 6.00 PM
Pre- bid conference	:	20.06.2024 at 11.00 A.M. (RMSC Board Room)
Last date and time of submission of online bids	:	09.07.2024up to 6.00 PM
Date and time of opening of Online technical bids	:	10.07.2024at 11 AM
Cost of the Bid Document	:	**Rs. 2360/- (including GST @ 18%)**
Cost of Bid Document For MSME Unit of Rajasthan		**Rs. 1180/- (including GST @ 18%)**
RISL Processing Fees	:	**Rs. 590/- (including GST @ 18%)**
Empanelment Fee	:	**Rs. 5900--/- (including GST @ 18%)**
Estimated Cost	:	**Rs. 40.98 Lakh**

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
RAJASTHAN

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF SURGICAL & SUTURES/MEDICAL DEVICES (Ending on 30.09.2026)

1. LAST DATE FOR RECEIPT OF BIDS, BID FEES, BID SECURITY, RISL PROCESSING FEES AND EMPANELMENT FEES

a) E-Bids [In Two Separate Bids (Technical Bid & Price Bid)] will be received till 06:00 PM on 09.07.2024 By The Rajasthan Medical Services Corporation Ltd, For the Empanelment of Analytical Testing Laboratories for the Test and Analysis Of SURGICAL & SUTURES/MEDICAL DEVICES (**Ending on 30.09.2026**) in English language. Proposal received after the closing date and time shall not be considered.

b) The bids shall be valid for a Period of 120 days from the date of opening of Technical Bid and prior to the expiration of the bid validity the Bid Inviting Authority may request the Bidders to extend the bid validity period for an additional specified period of time. The Bidder may refuse extension of bid validity, and in such a case its Bid Security deposit shall not be forfeited.

C) The Bids will be received on e-procurement web-portal of Govt. of Rajasthan. Every Bidder will be required to pay the following fees:

- Bid form fee Rs. 2360.00 (including GST @18%) (Rs. 1180.00 (including GST @18%) for MSME Units of Rajasthan) for downloading from the website.
- **Bid Security Deposit - Rs. 20,000/-**
- **Processing fee of Rs. 590 (including GST @18%) of R.I.S.L.**

These fee are to be paid through three separate prescribed challans (format enclosed in Annexure- I) in any branch of the BANK OF MAHARASHTRA Account no.-60460019022 & IFSC Code no. MAHB0000389 throughout country upto 09.07.2024 upto 6.00 P.M or through D.D. / bankers cheque in favour of M.D. RMSCL (Bid document fees and Bid security/ M.D. RISL (Bid processing fees) physically in the office of RMSCL on 09.07.2024 upto 06.00 PM. The bidders shall submit/upload scanned copy of all the challans/DD in Technical Bid. Bids will be opened only after ensuring receipt of Bid document fees along with processing fees and Bid Security Deposit. In the absence of Bid document fees and processing fees and Bid Security Deposit Rs. 20,000/- the Bids will be

rejected and will not be opened. Note:- (I) While the Bid uploading it would be asked on e procurement website about Bid Security, whether it is Rs. 20,000/- the bidder may mention any option for the purpose of Bid uploading but has to submit required Bid Security.

Click on offline mode (either DD or BC) on e procurement portal for the purpose of bid uploading only.

(a) Empanelment as analytical testing laboratories for the test and analysis of surgical & sutures/medical devices are required to deposit separately an Empanelment Fee of Rs 5900 (with GST @18%) (Five Thousand Nine Hundred rupees only) in the form of DD (in favour of MD, RMSCL)/challan before due time and date of bid submission.

2. <u>Eligibility Criteria for Empanelment :-</u>

(1) Testing Laboratories should have valid certificate of registration for carrying out test on (surgical & sutures) medical devices under the Drugs and Cosmetics Act, 1940 and medical device rule 2017.

Three years standing in the test & analysis of medical devices /Surgical & Sutures/drugs and the lab shall be entitled for empanelment for the categories of items for which lab is having registration / approval.

Bid is invited from CDSCO (on form no. MD-40) approved testing laboratory situated in India.

(2) Laboratory should have CDSCO registration (MD-40 with valid scope as defined in this certificate) as per medical device rule 2017, and NABL accreditation with scope for testing of Surgical & Sutures.

- ***The laboratory should be GLP compliant under the provisions of* the Drugs and Cosmetics Act, 1940, medical device rule 2017 *and Rules there under and should hold schedule L-1 certificate or should have approval from Drug Control Department* and NABL accreditation with proper scope of accreditation to undertake testing of drug items.**

(3) The laboratory should have an average annual turnover of **not** less than **Rs. 1 Crore** for past preceding three years **(2019-20, 2020-21, 2021-22)** or **(2020-21, 2021-22, 2022-23)** The same should be supported by audited annual accounts

& certified by a Chartered Accountant, based on audited accounts. (ANNEXURE-II)

No provisional accounts shall be accepted.

(4) The lab should have undertaken test and analysis of surgical & sutures of least three government institutions/corporation/reputed manufacturers.

(5) The lab should not stand banned / debarred or blacklisted by any State **or** Central Government Organizations or its central procurement agencies on the due date of bid submission. If a bidder or an approved bidder will be found defaulter for concealing this fact, then following actions may be taken.

(i) Bid rejection

(ii) Bid Security forfeiture

(iii) Agreement rejection

(iv) Performance Security forfeiture

(v) Blacklisting

(6) The laboratory and its responsible persons should not have been convicted under the provisions of applicable laws with regard to the activities and conduct of the laboratory.

(7) The laboratory should have all necessary instruments/equipments/machines for testing of medical devices, surgical & sutures as per standards laid down in drugs & cosmetics Act/ Pharmacopoeia/ Bureau of Indian Standards and other standards as applicable/ desired.

(8) <u>The bidder must follow Test Parameter given for individual item in Annexure – VII</u>.

(9) <u>Bidder must have Non-conviction Certificate issued by the State Licensing Authority/Central Licensing Authority.</u>

3 TECHNICAL BID

The Bidder must furnish the following in technical bid.

a. Bidders are allowed the option to quote for anyone item or more items as mentioned in bid (list of surgical &sutures proposed for testing at Annexure-VII). The bidder

has to mentioned type of test for each item, the filled up annexure VII to be submitted with technical bid.

NOTE: - Bidders have to mentioned/quote all the test parameters compulsorily in annexure-VII, If any bidder does not mention/quote any parameter/parameters, then the bid shall be treated as non-responsive for that particular item.

b. The bidders shall submit/upload scanned copy of all the challans, D.D./ BC, annexed with Technical Bid in proof of deposition/ submission of Bid document fees, RISL processing fee and Bid Security in case deposited in any branch of PNB throughout country. The required Bid Security Deposit / Bid document fees/ RISL fee may be in form of physical D.D. / BC and should be in favour of M.D. RMSCL (bid document fees and Bid Security Deposit) and M.D. RISL (bid processing fees).

c. Attested Photocopy of Analytical approval duly renewed up to date, issued by the State Licensing Authority.

d. CDSCO registration (MD-40) and Copy of NABL accreditation with scope for testing of Surgical & Sutures.

e. Documentary evidence of having analyzed Surgical & Sutures/ medical devices, for the last three years with a statement in the Performa as given in Annexure III.

f. Attested copy of certificate of registration for service GST.

g. Bidder must have Non-conviction Certificate issued by the State Licensing Authority/Central Licensing Authority.

h. Annual turnover statement for last 3 year i.e. **2019-20, 2020-21, 2021-22 or 2020-21, 2021-22, 2022-23** (ANEXURE-II) certified by the practicing Chartered Accountant with UDIN No.

i. Copies of the Balance Sheet and Profit and Loss Account for three years i.e. **2019-20, 2020-21, 2021-22 or 2020-21 2021-22, 2022-23 (Audited Accounts)** duly audited or certified by the practicing Chartered Accountant.

j. The following information in the form given in Annexure IV (a) to IV (d).

   a) The list of permanent technical qualified personnel employed in the laboratory with proof of their qualifications and relevant approvals.

b) The list of sophisticated instruments available in the laboratory.

c) Micro Biological facilities available in the laboratory.

d. In the case of Non- Pharmacopoeia Products the Method of Analysis Should be appended to the Report, especially if the sample is declared as "not of standard quality".

k. A declaration in the performa given in Annexure V duly signed and notarized.

l. Details of Laboratory in Annexure – VI.

m. A copy of PAN issued by Income GST Department.

n. GST return of last three months from bid submission end date.

o. The instruments such as power of attorney, resolution of board etc., authorizing an officer of the Bidder should be enclosed.

p. Documentary evidence for the constitution of the company / concern.

q. At any time prior to opening of price bid RMSC either at their own initiate or in response to clarification requested by prospective tender, may modify tender by issuing an amendment. Such amendments shall be loaded on E-Proc site and will be the part of tender.

r. Bidders have to fill up the checklist Annexure–VIII. the infrastructure and testing facilities available in the lab.

s. Compliance of Schedule L-1 of Drugs & Cosmetics Rules, 1945 (GLP certificate) and medical device rule 2017 and Copy of NABL accreditation with scope for testing of drug formulations.

4 PRICE BID:

The price bid will also be known as financial document and every bidder will be required to submit its price in excel format attached to the bid document (BOQ). **BOQ template must not be modified/ replaced by the bidder and the same should be uploaded after filling the relevant columns, else the bidder is liable to be rejected for this bid. Bidders are allowed to enter the bidder name and**

values only. **The bidder should quote rate for the complete tests as applicable to the item. The rate for sterility test for sterile products should also be quoted separately at last entry of BOQ. Any type of uncalled for clarification on prices and or rebates shall not be accepted.**

*** For item antibacterial coating bidders should quote the rates including Antibacterial test wherever applicable.**

5 OPENING OF TECHNICAL BID AND FINANCIAL BID EVALUATION

1. There after the Bidders found eligible as stated above on the basis of the examination on technical bid, the financial bid will be opened and after scrutiny thereof, including inspection of the laboratory, if required, the acceptable rates for analysis will be decided and communicated.

6 BID SECURITY

The Bid Security shall be Rs. 20,000/- paid through separate prescribed challan (format enclosed in Annexure-I) in any branch of the MAHARASHTRA Account no.-60460019022 & IFSC Code no. MAHB0000389 throughout country up to **……..** or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSCL on or before **……** up to 6.00 PM. Bid Security Deposit in any other form will not be accepted.

The Bids submitted without sufficient Bid Security will be summarily rejected. The Bid Security will be forfeited, if the Bidder withdraws its Bid after last time & date fixed for receiving bids or in the case of a successful Bidder, if the Bidder fails within specified time to sign the contract agreement or fails to furnish the security deposit.

Government undertaking PSU is exempted for Bid Security deposition on producing the certificate issued by the competent authority.

7 GENERAL CONDITIONS

1. The details of the surgical & sutures, to be analyzed shall be given in **Annexure VII**.
2. The Bidder should quote the rates for complete analysis of each product and name of test to be performed, methodology to be used for each test should be mentioned in **Annexure-VII**. **However wherever rates for individual test are demanded, they**

should be furnished accordingly in BOQ. Wherever test is prescribed and their name and methodology for testing are not stated, such lab will not be considered responsive testing for such item.

3. The rates quoted should be exclusive of GST.
4. The rates quoted and accepted will be binding on the Bidder for the stipulated period and on no account any revision will be entertained till the completion of the BID period.
5. Analytical Laboratory, which also has its manufacturing activity, if empanelled by RMSC, then Samples of its own manufacturing unit shall not be sent to its empanelled laboratory for testing.
6. The laboratory will not be permitted to outsource any test from other laboratory.
7. RMSCL shall have the right to cause the laboratory to be inspected by the members of its technical committee before opening of price bid and subsequently as and when considered appropriate and based on the finding, the Bidder may be disqualified or de-empanelled, as the case may be.
8. Conditional tender will not be accepted and rejected immediately.

8. ACCEPTANCE OF BID

1. The Bid evaluation committee formed by Managing Director, Rajasthan Medical Services Corporation Ltd. will evaluate the Bid with reference to various criteria.
2. The Managing Director, Rajasthan Medical Services Corporation Limited reserves the right to accept or reject any BID for any one or more of the items Bided for, without assigning any reason.
3. The Managing Director, Rajasthan Medical Services Corporation Limited has the right to accept one or more bidders depending on the volume of analytical work.

9. AGREEMENT

1. **The agreement with empanelled laboratories will remain valid up to 30.09.2026. If required period of contract can be extended up to 3 months same rate, terms and condition without any prior consent and shall be binding on approved bidder.**
2. RMSCL will issue letters of Intent (LOIs) to successful bidders and bidders who are empanelled will have to execute an agreement on a non- judicial stamp paper of value **Rs. 500 /-** (Stamp duty to be paid by the Bidder), in favour of

Managing Director, Rajasthan Medical Services Corporation Limited Jaipur within 15 days from the date of receipt of the intimation to them informing that their BIDs have been accepted. The format of agreement will be issued by RMSCL.

3. The Bidder shall not, at any time, assign, sub-let or make over the contract or the benefit therefore or any part thereof to any person or persons whatsoever.

4. All notices or communication relating to, or arising out of this agreement or any of the terms thereof shall be considered duly served on or given to the Bidder if delivered to him or left at the premises, places of business or abode.

10. PERFORMANCE SECURITY

1. The successful Bidders shall be required to pay a security deposit of **Rs. 50,000/-** ***in the form of demand draft*** at the time of execution of the agreement. **Performance security will be refunded three month after expiry of rate contract subject to successful completion of services.**

11. COMPLETE ANALYSIS & REPORTING CONDITIONS

1. (a) On empanelment and entrustment of the job, the Analytical Laboratory should furnish the test reports within:

(i) 10 days from the receipt of the sample in case of (non – sterile products)

(ii) 21 days from the receipt of the sample of surgical & sutures requiring test for sterility.

b) All the tests mentioned in BIS/ISO/IP/BP/USP/Drugs & Cosmetics Act. etc. including addendum/amendments, (as the case may be) should be carried out for each and every sample. The results obtained in the test should be mentioned in numerical value (wherever possible). However this condition will not

for past
for past
for past

apply when only specific testing is called for/desired on any particular sample. If IS/ISO Or pharmacopeia standards do not exists for any surgical and suture items

at the time bid opening but are declared later on, the item should be tested as per such standards.

c) "COMPLIES" or "PASSES" in the result column of the report is treated as incomplete report, if the result has some numerical value.

d) Every test report must have remarks either as "Standard Quality" or "Not of Standard Quality". Any ambiguity/cutting in reports will not be accepted (clear mention of "standard quality or not of standard quality" should be stated in bold letters and crossing/cutting of one of these will not be accepted).

e) Reports should be in A4 size (8.27" X 11.69") paper of good quality.

f) Report should be issued on form 39 and should have S. No. , name of drug sample, code no., batch no., mfg. date, exp. date, description of tests, protocol of test specified & applied, findings & results obtained and should be signed by person-in-charge of testing. In case of Not of Standard Quality Reports the reports shall be release on Pink/Red colored paper for easy identification of NOSQ drugs.

g) Reports should be attached along with Spectra / Chromatography data sheets, if applicable and it will be considered incomplete if spectra or chromatograms are not attached.

2. All test reports of each batch of sample should be submitted to the RMSC in triplicate. In case of failure of a sample, the result should be communicated immediately to the Executive Director (Q.C.) through phone / E-mail and the report should be sent along with protocol.

3. If in any circumstances (like break down of instrument, non-availability of reference standard etc.) the Analytical Laboratory is unable to undertake analysis for a sample, the same should be reported within 24 hours of receipt of such a sample by phone or E-mail and the sample should be returned to the Executive Director (Quality Control), Rajasthan Medical Services Corporation Limited, Jaipur after taking necessary telephonic or mail consent. In case of inability of laboratory to undertake the testing, a penalty of 25% of testing charges applicable for that product / products will be recovered.

4. If standard test procedure of any product is required the same should be demanded within 48 hours with return request. Period lapsed/taken in providing standard testing procedure will be condoned from prescribed time limit for that sample. Any distinct parameter of a product the testing procedure of which is not given in the IS / pharmacopoeia, is to be tested as per manufacturer STP or other standard procedure.
5. If any sample is received in a damaged condition by the laboratory, the sample should not be analyzed and the information should be sent immediately to the E.D. (Quality Control), Rajasthan Medical Services Corporation Limited Jaipur by Fax or E-mail.
6. The Managing Director, Rajasthan Medical Services Corporation Limited or his authorized representative(s) has / have the right to inspect the laboratories of the Bidders who have submitted BIDs, before taking any decision regarding empanelment. Similarly, the Managing Director, Rajasthan Medical Services Corporation Limited or his authorized representatives may also inspect any empanelled laboratory, at any point of time during the continuance of the BID and terminate / cancel its empanelment or any orders issued to the laboratory, not to entrust any further testing job to the laboratory based on facts brought out during such inspections.
7. The qualified/empanelled lab shall have to make own arrangement for collection of sample, from RMSC Headquarters.
8. It will be sole discretion of RMSC to allot the samples to any empanelled lab in case when there are more than one lab approved for an item. (One or more Laboratories may be empanelled by this tender.)

12. PAYMENT PROVISIONS

1. No advance payment towards any analysis will be made to the empanelled Bidder.
2. No payment will be made for the incomplete analysis or incomplete report. Deliberate omission of any critical test will be viewed seriously and shall invite action against the laboratory as deemed fit by RMSCL.

3. Payments towards the analysis of Drugs will be made as per approved rate plus GST on it will be along with GST at the prevailing rate as applicable at the time of payment.

13. PENALTIES

1. If the successful Bidder fails to execute the agreement and payment of security deposit within the time specified or withdraws the BID after intimation of the acceptance of the BID has been sent to or owing to any other reasons, he is unable to undertake the contract, the empanelment will be cancelled and the Bid Security deposited by the Bidder shall stand forfeited in favour of the Rajasthan Medical Services Corporation Limited. Such Bidder(s) will also be liable for all damages sustained by the Rajasthan Medical Services Corporation Limited due to of breach of BID conditions. Such damages shall be assessed by the Managing Director, Rajasthan Medical Services Corporation Limited whose decision shall be final.
2. Non performance of any BID or empanelment conditions will disqualify a laboratory to participate in the BID for the period as decided by RMSCL.
3. If it is revealed that the analytical Laboratory is involved in any form of fraud and collusion with the suppliers of Rajasthan Medical Services Corporation Limited, the Analytical Laboratory will be black listed for a period considered suitable. The Bidders shall also be liable for action under criminal law and the matter will be notified to the concerned Director of Drugs Control for suitable action against them under Drugs & Cosmetics Act & Rules.
4. The Managing Director, Rajasthan Medical Services Corporation Limited will be at liberty to terminate without assigning any reasons, the empanelment of any laboratory either wholly or in part at one month's notice. The Bidder will not be entitled for any compensation whatsoever in respect of such termination.
5. In all matters pertaining to the BID, the decision of the Managing Director, Rajasthan Medical Services Corporation Limited shall be final and binding.

6. (i) If the laboratory requires an extension in time for submission of test report, on account of occurrence of any hindrance he shall apply in writing for extension on occurrence of hindrance but not after the stipulated date of ***furnishing the test report***.

(ii) The Executive Director (QC)/ Drug Controller/ADC (QC) may extend the testing period with or without liquidated damages in case they are satisfied that the delay in the submission of test reports is on account of any hindrances, he shall apply in writing for extension on occurrence of hindrance but not after the stipulated date of submission of report. Reasons shall be recorded.

(iii) **Extension in testing period:-** In case of extension in the testing period with liquidated damages the recovery shall be made on the basis of following percentages of ***testing charges*** which the Bidder has failed to submit:-

(a) Delay upto one fourth period of the prescribed testing period; 2.5%

(b) Delay exceeding one fourth but not exceeding half of the prescribed testing period; 5%

(c) Delay exceeding half but not exceeding three fourth of the prescribed testing period; 7.5%

(d) Delay exceeding three fourth of the prescribed testing period; 10%

Note: Fraction of a day in reckoning period of delay in ***furnish the test report*** shall be eliminated if it is less than half a day. The maximum amount of liquidated damages shall be 10%.

iv. If, at any time during the continuance of this Agreement, the ***laboratory*** has, in the opinion of the Purchaser, delayed in submitting any test report, by the reasons of any riots, mutinies, wars, fire, storm, earthquakes, tempest or other exceptional cause, on a specific request made by the laboratory, the time for submitting test report may be extended by the ***RMSCL*** purely at his discretion for such period as may be considered reasonable. No further representation from the ***laboratory*** will be entertained on this account.

14. CORRECTION OF ARITHMETIC ERRORS:

Provided that a financial bid is substantially responsive, the procuring Entity will correct arithmetical errors during evaluation of Financial Bids on the following basis:

(i) If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail and the total price shall be corrected, unless in the opinion of the Procuring Entity there is an obvious misplacement of the decimal point in the unit price, in which case the total price as quoted shall govern and the unit price shall be corrected;

(ii) If there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected; and.

(iii) If there is a discrepancy between words and figures, the amount in words shall prevail, unless the amount expressed in words is related to an arithmetic error, in which case the amount in figures shall prevail subject to clause (a) and (b) above.

If the Bidder that submitted the lowest evaluated bid does not accept the correction of errors, its Bid shall be disqualified and its Bid Security shall be forfeited or its Bid Securing Declaration shall be executed.

15. GRIEVANCE REDRESSAL DURING EMPANELMENT PROCESS:

The Designation and address of the First Appellate Authority is Mission Director National Health Mission, Rajasthan , Jaipur.

The Designation and address of the Second Appellate Authority is Additional Chief Secretary, Medical, Health & Family Welfare, Govt. of Rajasthan and Chairman, RMSCL.

i. Filling an appeal

If any Bidder or prospective bidder is aggrieved that any decision, action or omission of the Procuring Entity is in contravention to the provisions of the Act or the Rules of the Guidelines issued there under, he may file an appeal to First Appellate Authority, as specified in the Bidding Document within a period of ten days from the date of such decision or action, omission, as the case may be, clearly giving the specific ground or ground on which he feels aggrieved:

Provided that after the declaration of a Bidder as successful the appeal may be filed only by a Bidder who has participated in procurement proceedings:

Provided further that in case a Procuring Entity evaluates the Technical Bids before the opening of the Financial Bids, an appeal related to the matter of Financial Bids may be filed only by a Bidder whose Technical Bid is found to be acceptable.

ii. The Officer to whom an appeal is filed under Para (1) shall deal with the appeal as expeditiously as possible and shall Endeavour to dispose it of within thirty days from the date of the appeal.

iii. If the officer designated under Para (1) fails to dispose of the appeal filed within the period specified in Para (2), or if the Bidder or prospective bidder or the Procuring Entity is aggrieved by the order passed by the First Appellate Authority, the Bidder or prospective bidder or the Procuring Entity, as the case may be, may file a second appeal to second Appellate Authority specified in the Bidding Document in this behalf within fifteen days from the expiry of the period specified in Para (2) or of the date of receipt of the order passed by the First Appellate Authority, as the case may be.

iv. Appeal not to lie in certain cases

No appeal shall lie against any decision of the Procuring Entity relating to the following matters, namely:-

(a) Determination of need of empanelment;

(b) Provision limiting participation of Bidders in the Bid process; (c) The decision of whether or not to enter into negotiations;

(d) Cancellation of a empanelment process;

(e) Applicability of the provisions of confidentiality.

v. Form of Appeal

(a) An appeal under Para (1) or (3) above shall be in the annexed Form along with as many copies as there are respondents in the appeal.

(b) Every appeal shall be accompanied by an order appealed against, if any, affidavit verifying the facts stated in the appeal and proof of payment of fee.

(c) Every appeal may be presented to First Appellate Authority or Second Appellate Authority, as the case may be, in person or through registered post or authorized representative.

vi. Fee for filling appeal

(a) Fee for first appeal shall be rupees two thousand five hundred and for second appeal shall be rupees ten thousand, which shall be non-refundable.

(b) The fee shall be paid in the form of bank demand draft or banker's cheque of a Scheduled Bank in India payable in the name of Appellate Authority concerned.

vii. Procedure for disposal of appeal

(a) The First Appellate Authority or Second Appellate Authority, as the case may be, upon filling of appeal, shall issue notice accompanied by copy of appeal, affidavit and documents, if any, to the respondents and fix date of hearing.

(b) On the date fixed for hearing, the First Appellate Authority or Second Appellate

Authority, as the case may be, shall,-

(i) Hear all the parties to appeal present before him; and

(ii) Peruse or inspect documents, relevant records or copies thereof relating to the matter.

(c) After hearing the parties, perusal or inspection of documents and relevant records or copies thereof relating to the matter, the Appellate Authority concerned shall pass an order in writing and provide the copy of order to the parties free of cost.

(d) The order passed under sub-clause (c) above shall be placed on the State Public procurement Portal.

16. <u>COMPLIANCE WITH THE CODE OF INTEGRITY AND NO CONFLICT OF INTEREST:</u>

Any person participating in an empanelment process shall-

a) Not offer any bribe, reward or gift or any material benefit either directly or indirectly in exchange for an unfair advantage in procurement process or to otherwise influence the procurement process;

b) Not misrepresent or omit misleads or attempts to mislead so as to obtain a financial or other benefit or avoid an obligation;

c) Not indulge in any collusion, Bid rigging or any-competitive behavior to impair the transparency, fairness and progress of the procurement process;

d) Not misuse any information shared between the procuring Entity and the Bidders with an intent to gain unfair advantage in the procurement process;

e) Not indulge in any coercion including impairing or harming or threatening to do the same, directly or indirectly, to any part or to its property to influence the procurement process;

f) Not obstruct any investigation or audit of a procurement process;

g) Disclose conflict of interest, if any; and

h) Disclose any previous transgressions with any Entity in India or any other country during the last three years or any debarment by any other procuring entity.

17. Conflict of interest:-

The Bidder participating in a bidding process must not have a Conflict of Interest.

A Conflict of interest is considered to be a situation in which a party has interests that could improperly influence that party's performance of official duties or responsibilities, contractual obligations, or compliance with applicable laws and regulations.

I. A Bidder may be considered to be in Conflict of interest with one or more parties in bidding process if, including but not limited to:

a. Have controlling partners/shareholders in common; or

b. Receive or have received any direct or indirect subsidy from any of them; or

c. Have the same legal representative for purposes of the Bid; or

d. Have a relationship with each other, directly or through common third parties, that puts them in a position to have access to information about or influence on the Bid of another Bidder, or influence the decisions of the Procuring Entity regarding the bidding process; or

e. The Bidder participates in more than one Bid in a bidding process. Participation by a Bidder in more than one Bid will result in the disqualification of all Bids in which the Bidder is involved. However, this does not limit the inclusion of the same subcontractor, not otherwise participating as a Bidder, in more than one Bid; or

f. The Bidder or any of its affiliates participated as a consultant in the preparation of the design or technical specification of the Goods, Works or Services that are the subject of the Bid; or

g. Bidder or any of its affiliates has been hired (or is proposed to be hired0 by the Procuring Entity as engineer-incharge/ consultant for the contract.

18. JURISDICTION

1. In the event of any legal dispute arising out of the BID such dispute would be subject to the jurisdiction of the Civil courts within the city of Jaipur only.

19. APPLICABILITY OF RULES

Besides above conditions the provisions of RTPP Act 2012 & RTPP Rule 2013 will be applicable.

Managing Director
Rajasthan Medical Services Corporation

Annexure - 1

CAUTION : USE "FCMBR" MENU OPTION IN FINACLE INSTEAD OF "TM"

BANK of MAHARASHTRA — Bank Copy

DIST. NO.

Branch

Institute Name: Rajasthan Medical Services Corporation, Jaipur

Institute ID: RMSCJ - A/c No. 60460019022

Date of Deposit: DD MM YY

DETAILS OF THE SUPPLIER

Supplier Name

Tender Ref. No.

Type of Deposit: Select any one out of - Tender Fees/EMD/SD/Tender Processing fees/Others

Mobile No.

Cash Deposit:

Denomination	₹	Ps
1000 *		
500 *		
100 *		
50 *		
20 *		
10 *		
5 *		
Coins *		
Total		

Cheque Deposit:

Chq No	Date of Chq	Name of Bank	₹	Ps

Total fee payable ₹

Commission ₹ 0 0 0 0 0 - 0 0

Total amount ₹ -

Amount (in words): ₹

Name of the Depositor

Signature

Address for communication

For Bank use only

Acknowledgement

Cashier/Officer

Bank of MAHARASHTRA — Customer Copy

DIST. NO.

Branch

Institute Name: Rajasthan Medical Services Corporation, Jaipur

Institute ID: RMSCJ - A/c No. 60460019022

Date of Deposit: DD MM YY

DETAILS OF THE SUPPLIER

Supplier Name

Tender Ref. No.

Type of Deposit: Select any one out of - Tender Fees/EMD/SD/Tender Processing fees/Others

Mobile No.

Cash Deposit:

Denomination	₹	Ps
1000 *		
500 *		
100 *		
50 *		
20 *		
10 *		
5 *		
Coins *		
Total		

Cheque Deposit:

Chq No	Date of Chq	Name of Bank	₹	Ps

Total fee payable ₹

Commission ₹ 0 0 0 0 0 - 0 0

Total amount ₹ -

Amount (in words): ₹

Name of the Depositor

Signature

Address for communication

For Bank use only

Acknowledgement

Cashier/Officer

37

22

ANNEXURE-II

Ref. Clause No. 2 (3), 3(h)

ANNUAL TURN OVER STATEMENT

The Annual Turnover of M/s._____ for the past three years are given below and certified that the statement is true and correct.

S.No.	Years	Turnover in Crore (INR.)
1	2019-20	
2	2020-21	
3	2021-22	
Total		**Rs.** **Crore**
Average Annual Turnover		**Rs.** **Crore**

OR

S.No.	Years	Turnover in Crore (INR.)
1	2020-21	
2	2021-22	
3	2022-23	
Total		**Rs.** **Crore**
Average Annual Turnover		**Rs.** **Crore**

Date:

Seal:

UDIN NO.

Signature of Auditor/
Chartered Accountant

(Name in Capital)

ANNEXURE III
Ref. Clause No: 3 (e)

PROFORMA FOR PERFORMANCE STATE MENT
(for a period of last 3 years)

Name of the Laboratory : _____

Address:_____

_____

Types of Samples Analyzed No. of Samples Analyzed during
(2020-21, 2021-22, 2022-23 or 2021-22, 2022-23, 2023-24)

01. Surgical (Specify item names)

02. Sutures (Specify types)

03. Implants

04. Devices

Signature :
Date :
Name of the Lab :
Office Seal :

ANNEXURE – IV (a)
Ref. Clause No: 3 (j) (a)

PERSONNEL IN QC DEPARTM ENT

Name of the Technical Staff approved by State Licensing Authority along with his Designation, Highest Qualification, Experience (Experience relevant to analysis of drugs/surgical/sutures)

Signature :

Date :

Nam e of the Lab :

Office Seal :

ANNEXURE – IV (b)
Ref. Clause No: 3(j) (b)

LIST OF SOPHISTICATED EQUIPMENT/INSTRUMENT/APPARATUS AVAILABLE IN THE LAB THAT ARE USE IN TESTING OF MEDICAL DEVICE/SURGICAL & SUTURE

S.No.	Name of the Equipment Instruments / Apparatus	Make & Description	Date of Installation	Date of last Validation	Approved for testing of drugs from State licensing Authority since……..

Signature :

Name of the Lab :

Date :

Official Seal:

ANNEXURE – IV (C)
Ref. Clause No: 3(j) (c)

FACILITIES IN THE MICROBIOLOGICAL SECTION

I. LIST OF STOCK CULTURES AVAILABLE

II. LIST OF EQUIPMENT / APPARATUS AVAILABLE WITH DATE OF INSTALLATION, make and approval from State Licensing Authority to permit microbiological testing in the Lab.

Signature :

Name of the Lab :

Date :

Official Seal:

ANNEXURE – IV (d)
Ref. Clause No: 3(j) (d)

LIST OF REFERENCES SAMPLES ALONG WITH THEIR DATE OF PROCUREMETN AND QUANTITIES

Signature :

Name of the Lab :

Date :

Official Seal:

Affidavit

(on Non Judicial Stamp of Rs.100/-)

ANNEXURE – V
Ref. Clause No: 3(k)

DECLARATION FORM

1. I (Name of the Bidder) S/O_____, Age_____, resident of_____, am proprietor /Partner/Director having our office at_____ and the CDSCO registered (Surgical & Sutures) medical devices testing laboratory at_____do hereby declare that I have carefully read all the conditions of BID of Rajasthan Medical Services Corporation Ltd., Jaipur, for the BIDs floated for empanelment of approved NABL testing laboratories for analysis of surgical & sutures/medical devices. (Ending on ----------) and shall abide by all the conditions set forth therein.
2. I further declare that I possess valid approval for testing of all the surgical & sutures/medical devices for which Price Bid have been submitted by me/us in Cover B and permission on CDSCO-Form 40 have been obtained for testing of these items from Licensing Authority where ever applicable.
3. That the approval to test surgical & sutures/medical devices have been obtained on CDSCO-Form 40 bearing No._____which is valid/renewed up to_____.
4. That the Bidder firm is a proprietorship/Partnership/Pvt. Ltd./ltd. firm and following are the other partners/directors:-

S.No.	Name of Partner/Director	Age	Present & Permanent Address

5. That our laboratory/Firm/Company does not stand blacklisted /debarred or banned on any ground either by Bid Inviting Authority or Govt. of Rajasthan on the date of bid submission.

Our laboratory/Firm/Company also does not stand blacklisted, debarred or banned on the ground of **wrong reporting of test results** or on the ground of submission of fake or forged documents or false information / facts, by any State or Central Government or by its central drug procurement agencies, on the date of bid submission for supply of drugs/medicines in India.

6. That I/We have carefully read all the conditions of bid in Ref. No**.:** F.02(173)/RMSCL/LAB EMPANELMENT(S&S)/NIB-10/2024/3622 Dated:- 12.06.2024

   For the empanelment of analytical testing laboratories for the test and analysis of SURGICAL & SUTURES/MEDICAL DEVICES (Ending on 30.09.2026) for Rajasthan medical services corporation and accept all conditions of bid, including amendments if any. That we have testing facilities as per testing parameters mentioned in Annexure VII and quoted for products as given below:-

Sr No.	**Quoted item Code No. (as per mention in Annexure-VII)**
1.	
2.	
3.	
.	
.	

7. I/ we hereby declare under Section 7 of Rajasthan Transparency in Public Procurement Act, 2012. that:
   a. I/we possess the necessary professional, technical, financial and managerial resources and competence required by the Bidding Document issued by the Procuring Entity;
   b. I/we have fulfilled my/our obligation to pay such of the GST payable to the Union and the State Government or any local authority as specified in the Bidding Document;
   c. I/we are not insolvent, in receivership, bankrupt or being wound up. not have my/our affairs administered by a court or a judicial officer, not have my/our business activities suspended and not the subject of legal proceedings for any of the foregoing reasons;
   d. I/we do not have, and our directors and officers not have, been convicted of

any criminal offence related to my/our professional conduct or the making of false statements or misrepresentations as to my/our qualifications to enter into a procurement contract within a period of three years preceding the commencement of this procurement process, or not have been otherwise disqualified pursuant to debarment proceedings;

e. I/we do not have a conflict of interest as specified in the Act, Rules and the Bidding Document, which materially affects fair competition;

8. Our complete address for communication with phone no.:- ----------

PAN of the Lab:- ----------

9. E mail address :- ----------
10. Bank detail for e banking :-

Name of account holder ……

Full name of Bank with Branch ……

A/c no. with full digits……..

IFSC code ……..

(Deponent)

Signature :

Date :

Name of the Lab :

Office Seal :

Verification

I……..S/o……(Designation)……. Affirm on oath that the contents/information from para 1 to 10 as mentioned above, are true & correct to the best of my knowledge and nothing is hidden. I also declare on oath, that if any information furnished by me as above is found wrong, false, forged or fabricated; the Corporation will be at liberty to cancel the Bid and forfeiting the earnest money deposit and or performance security, for which I shall be solely responsible and the laboratory / firm may be Debarred/Banned/ prosecuted for the same

(Name of Deponent & Signature)

ATTESTED BY NOTARY PUBLIC

ANNEXURE – VI
Ref.Clause No: 3 (l)

DETAILS OF LABORATORY

1. Name of the Laboratory & Full Address :

   Phone No (landline) :

   Fax :

   E-mail :

2. Other Branches & their Address (if any) :

3. Whether the firm has it own manufacturing unit? :

   If yes give details of address, license number etc.

4. Date of Inception :
5. CDSCO (FORM-40) REGISTRATION No. & Date :
6. Issued by :
7. Valid up to :
8. Schedule L-1 certificate its no. and date of issue (GLP) :
9. (i) NABL Accreditation no. & date
   (ii) Scope of Accreditation
   (iii) Its validity.
10. Name of the authorized signatory :
11. Specimen Signature of the authorized Signatory :
12. Names & Specimen Signatures of the Approved technical Staff who are authorized to sign the test reports :

ANNEXURE VII
(Item List & Test Parameter)
Clause 2(8)

S. No.	Code No	Name of Surgical Item	Testing parameters
1	NRS-5	Absorbable 5 mm Hernia mesh fixation device 30 screw shaped	Description
			Visual Test
			Tack length
			Number of Tacks
			Absorbability of Tacks
			Material of Tacks
			Shaft flexibility
			Firing Test
			Packaging & Labelling
2	NRS-6	Absorbable 5 mm Hernia mesh fixation device 15 screw shaped	Description
			Visual Test
			Tack length
			Number of Tacks
			Absorbability of Tacks
			Material of Tacks
			Shaft flexibility
			Firing Test
			Packaging & Labelling
3	NRS-7	Non absorbable 5 mm hernia mesh fixation device	Description
			Visual Test
			Tack dimension
			Number of Tacks
			Material of Tacks
			Firing Test
			Packaging & Labelling
4	NRS-15	Linear cutter 55mm with six rows	Description
			Visual Test : Free from scratches, burrs, cracks
			Dimension
			No. of staple rows
			Functional Test
			Firing
			Fitment of Cartridge
			Package seal
			Packaging & Labelling
			Sterility
5	NRS-16	Linear cutter 75mm with six rows	Description
			Visual Test : Free from scratches, burrs, cracks

			No. of staple rows
			Dimension
			Functional Test
			Firing
			Fitment of Cartridge
			Package seal
			Packaging & Labelling
			Sterility
6	NRS-17	Universal linear cutter cartridge 75mm	Description
			Visual Test : Free from scratches, burrs, cracks
			Dimension
			Functional Test
			Firing
			Fitment in Cutter
			Package seal
			Packaging & Labelling
			Sterility
7	NRS-18	Universal linear cutter cartridge 55mm	Description
			Visual Test : Free from scratches, burrs, cracks
			Dimension
			Functional Test
			Firing
			Fitment in Cutter
			Package seal
			Packaging & Labelling
			Sterility
8	NRS-19	Curved cutter stapler 40 mm linear cutter	Description
			Visual Test : Free from scratches, burrs, cracks
			Dimension
			Functional Test
			Firing
			Fitment of Cartridge
			Package seal
			Packaging & Labelling
			Sterility
9	NRS-20	Curved green cartridge having close staple height of 2.0 mm	Description
			Visual Test : Free from scratches, burrs, cracks
			Dimension
			Staple height
			Functional Test
			Firing
			Fitment in Cutter
			Package seal
			Packaging & Labelling

			Sterility
10	NRS-24	Laparoscopic cartridge for stapler 60 mm Blue, 1.5 mm	Description
			Visual Test : Free from scratches, burrs, cracks
			Number of staple rows
			Dimension
			Staple length
			Staple height
			Functional Test
			Firing
			Fitment in Cutter
			Package seal
			Packaging & Labelling
			Sterility
11	NRS-25	Laparoscopic cartridge for stapler 60 mm Green, 2.0 mm	Description
			Visual Test : Free from scratches, burrs, cracks
			Number of staple rows
			Dimension
			Staple length
			Staple height
			Functional Test
			Firing
			Fitment in Cutter
			Package seal
			Packaging & Labelling
			Sterility
12	NRS-26	Hemorrhoidal stapler kit consists of 33mm	Description
			Visual Test : Free from scratches, burrs, cracks
			Components of Kit
			Dimension
			Staple height
			Staple open leg length
			Functional Test
			Operation / Functionality of anvil
			Anastomosis Integrity Test
			Package seal
			Packaging & Labelling
			Sterility

13	NRS-30	Varied Staple Height reloads/cartridges for 60 mm GIA instruments	Description Visual Test : Free from scratches, burrs, cracks Tripple Row Stappling line Dimensions Functional Test Firing Fitment in Cutter Package Seal Packaging & Labelling Sterility
14	NRS-31	Varied Staple Height reloads/cartridges for 80 mm GIA	Description Visual Test : Free from scratches, burrs, cracks Tripple Row Stappling line Dimensions Functional Test Firing Fitment in Cutter Package Seal Packaging & Labelling Sterility
15	NRS-32	Linear cutter with Varied staple height Tri-Staple GIA 60 mm	Description Visual Test : Free from scratches, burrs, cracks Dimensions Functional Test Firing Fitment of Cartridge Tri-Staple enabled Package Seal Packaging & Labelling Sterility
16	NRS-33	EEA circular stapler Purple colour medium thick	Description Visual Test : Free from scratches, burrs, cracks Dimensions Tripple Row Stappling Functional Test Package Seal Packaging & Labelling Sterility
17	NRS-34	Linear cutter with Varied staple height Tri-Staple GIA 80 mm	Description Visual Test : Free from scratches, burrs, cracks Dimensions Functional Test Firing Fitment of Cartridge Tri-Staple enabled Package Seal Packaging & Labelling Sterility

18	NRS-42	Laparoscopic liner cutter with cartridges in sizes of 60mm	Description
			Visual Test : Free from scratches, burrs, cracks
			Dimension
			Functional Test
			Firing
			Fitment of Cartridges
			Knife
			Package seal
			Packaging & Labelling
			Sterility
19	NRS-43	Hand activated curved taper tip coagulating shears compatible focus 9	Description
			Visual Test : Free from scratches, burrs, cracks
			Curved Taper Tip
			Blade Length
			Functionality Tests
			Adaptibility for Different Tissues
			Hand Activation
			Device frequency slope test
			Blade function test
			Sealing Capacity
			Package seal
			Packaging & Labelling
			Sterility
20	NRS-44	Hand activated curved taper tip coagulating shears compatible focus 17	Description
			Visual Test : Free from scratches, burrs, cracks
			Curved Taper Tip
			Blade Length
			Functionality Tests
			Adaptibility for Different Tissues
			Hand Activation
			Device frequency slope test
			Blade function test
			Sealing Capacity
			Package seal
			Packaging & Labelling
			Sterility
21	NRS-45	Advance Bipolar Hand Activated probe with 5mm shaft diameter and 35 cm shaft length with 5 mm wide	Description
			Visual Test : Free from scratches, burrs, cracks and damages
			Dimensions
			Shaft Diameter
			Shaft Length
			Jaw dimension
			Functionality Tests

			Hand Activation
			Seal Length
			Cut Length
			Vessel Sealing
			Hipot Test for RF energy
			Temperature Control in Jaw
			Articulation Angle
			Rotation
			Knife Function
			Shaft Function
			Compatibility with Generator
			Open Circuit test for Shaft
			Short Circuit test for Shaft
			Force to Fire Test
			Package seal
			Packaging & Labelling
			Sterility
22	NRS-50	Advanced bipolar tissue sealer 37 cms, with 5mm shaft diameter, 24 mm Jaw length, 21.8 mm cut length and 13.4 mm	Description
			Visual Test : Free from scratches, burrs, cracks and damages
			Dimensions
			Shaft Diameter
			Shaft Length
			Jaw dimension
			Jaw Design
			Jaw Apperture
			Seal and Cut Buttons
			Functionality Tests
			Hand Activation
			Seal Length
			Cut Length
			Hipot Test for RF energy
			Temperature Control in Jaw (if applicable)
			Articulation Angle
			Shaft Rotation
			Knife Function
			Shaft Function
			Compatibility with Generator
			Open Circuit test for Shaft
			Short Circuit test for Shaft
			Force to Fire Test
			Package seal
			Packaging & Labelling
			Sterility
23	NRS-53	Connecting cable for ultrasonic harmonic scalpel for Open Energy with Focus Plus Shear- HP BLUE	Description
			Visual Test : Free from scratches, burrs, breaks and damages

			Dimensions
			Compatibility with ultrasonic disector
			Sterility
24	NRS-54	Connecting cable for ultrasonic harmonic scalpel for Lap Energy with Ace plus Shear HP054	Description
			Visual Test : Free from scratches, burrs, breaks and damages
			Dimensions
			Compatibility with ultrasonic disector
			Sterility
25	NRS-81	Curved tip & Stepped Cartridges face from inner to outer side 2.0,2.5 and 3.0 mm	Description Visual Test : Free from scratches, burrs, cracks Dimensions Functional Test Firing Fitment in Cutter In-built knife Package Seal Packaging & Labelling Sterility
26	NRS-82	Curved tip & Stepped Cartridges face from inner to outer side 3.0,3.5 and 4.0 mm	Description Visual Test : Free from scratches, burrs, cracks Dimensions Functional Test Firing Fitment in Cutter In-built knife Package Seal Packaging & Labelling Sterility
27	NRS-83	Varied Staple Height reloads/cartridges for 60 mm GIA	Description Visual Test : Free from scratches, burrs, cracks Dimensions Functional Test Firing Fitment in Cutter Tri-staple enabled In-built knife Package Seal Packaging & Labelling Sterility
28	NRS-87	Disposable 10 mm Endoscopic Clip Applier medium/large size	Description Visual Test : Free from scratches, burrs, cracks No. of Clips Clip metal test Firing Packing & Labelling Sterility

29	NRS-92	Disposable Clip Applier Preloaded with 20 clips Medium	Description Visual Test : Free from scratches, burrs, cracks No. of Clips Clip metal test Interlock security & design Firing Sterility Packing & Labelling
30	NRS-109	MICRO GUIDE WIRE For microcatheter shapable distal end and with torque 0.014inch	Description Dimensions Visual Test: Free from extraneous matter & surface defects Outside Diameter Tip shape / configuration Coating Corrosion Resistance Fracture Test Flexing Test Peak Tensile Force Torque 0.014 inch Sterility Packaging & Labelling
31	NRS-117	AORTIC PUNCH 4	Description Dimensions Visual Test for any defect / non-conformity Sharpness & Efficiency of Cut Edge Tip Shape & Configuration Handle Configuration Firing Test Sterility Packaging Labelling
32	NRS-118	AORTIC PUNCH 4.5	Same as NRS-117
33	NRS-121	AORTIC PUNCH 3.6	Same as NRS-117
34	NRS-128	bipsy Gun with compitible Co-axial needle 14gX11cm	Description Visual Tests Size of Gun Length of Shaft Compatibility with co-axial needle Firing Tests to be conducted as per product specifications; as per applicable standards.

35	NRS-134	bipsy Gun with compitible Co-axial needle 18gX11cm	Description Visual Tests Size of Gun Length of Shaft Compatibility with co-axial needle Firing Tests to be conducted as per product specifications; as per applicable standards.
36	NRS-135	bipsy Gun with compitible Co-axial needle 18gX15cm	Description Visual Tests Size of Gun Length of Shaft Compatibility with co-axial needle Firing Tests to be conducted as per product specifications; as per applicable standards.
37	NRS-151	Double wall Resuscitator with PEEP valve in Adult	Description Visual Test Components Single Shutter Valve Patient Valve Mask Connector between Valve and mask Splash Guard Oxygen Reservoir Bag Valve Disc Reservoir Tube Inlet Valve PEEP valve attachment Autoclavable Double Wall Resuscitator Drop Test Immersion in water Test High/ Low pressure test Delivered Oxygen Concentration Inspiratory Resistance Test Patient Valve Function Ventillation Performance Bag Volume Single Shutter Valve System Spontaneous Breathing Test Sterility Packaging & Labelling

38	NRS-152	Double wall Resuscitator with PEEP valve in Paediatrics	Description Visual Test Components Single Shutter Valve Patient Valve Mask Connector between Valve and mask Splash Guard Oxygen Reservoir Bag Valve Disc Reservoir Tube Inlet Valve PEEP valve attachment Autoclavable Double Wall Resuscitator Drop Test Immersion in water Test Patient valve function after contamination with vomitus High/ Low pressure test Delivered Oxygen Concentration Inspiratory Resistance Test Patient Valve Function Ventillation Performance Bag Volume Single Shutter Valve System Spontaneous Breathing Test Sterility Packaging & Labelling
39	NRS-155	Single Patient Use SEBS Resuscitator (SPUR II with Peep Valve in Neonatal)	Description Visual Test Components Single Shutter Valve Single Use Self-inflating Bag of thin SEBS material Pressure limiting Valve system Mask Swivel Connector between Valve and mask Splash Guard Compatible with Manometers and PEEP valve High/ Low pressure test Delivered Oxygen Concentration Inspiratory Resistance Test Ventillation Performance Bag Volume Single Shutter Valve System Spontaneous Breathing Test Sterility Packaging and Labelling
40	NRS-174	Offset Connector Cardio Sensor Electrodes Sizes –Adult	Tests to be conducted as per product specifications and as per applicable standards.

41	NRS-199	Volumetric Incentive Spirometer (ADULT)	Description Volume 4000 ml Particulate Filter Ergonomic Swiveled mouthpiece Volume measurement Flow indicator Flow Testing Drop Testing Leakage Test Tests to be carried as per product specification and applicable Standards/ Protocol.
42	NRS-200	Volumetric Incentive Spirometer (PEDIATRIC)	Description Volume 2500 ml Particulate Filter Ergonomic Swiveled mouthpiece Volume measurement Flow indicator Flow Testing Drop Testing Leakage Test Tests to be carried as per product specification and applicable Standards/ Protocol.
43	NRS-212	FHME Heat and moisture exchangers with Bacteria viral filters	Description Visual Test Bacterial Filter Viral Filter Bacterial / Viral Filtration Efficiency Material of Filter membrane: Hydrophobic non-woven polypropylene Sterility Tests as per product specifications and as specified in applicable Standards; ISO 9360-1
44	NRS-213	Tracheostomy HME:	Description Visual Test Components Bacterial / Viral Filtration In-built oxygen port Oxygen tubing: Kink Resistent Sampling & Suctioning Port Sterility Tests as per product specifications and as specified in applicable Standards; ISO 9360-2
45	NRS-237	Torque Device for .014" to .038" standard and hydrophilic guide wires with squeeze-load-release mechanism	As per product specifications

46	NRS-244	Angiography Wire PTFE Guidewire in .035", .038", in regular length	Description Visual Test: Free from extraneous matter and surface defects Length Outside Diameter Tip Design & Configuration Coating Fixed Core / Movable core Corrosion Resistance Radio detectable Fracture Test Flexing Test Peak Tensile Force Sterility Packing & Labelling
47	NRS-245	Angiography Wire Long Length PTFE Guidewire in .035", .038",	Same as NRS-244
48	NRS-248 (a)	Hydrophilic Wire Long Length Hydrophilic guidewire of .018", .025", .035", .038" in 180cm, 220cm, 260cm length	Description Dimensions Surface Finish Tip (conformity to specification) Radiopaque Jacket Nitinol core polyurethane jacket Guide wire Coating Torque Catheter compatibility Corrosion resistance Fracture Test Flexing Test Kink Resistance Peak Tensile Force Sterility Packing & Labelling
49	NRS-248(b)	Hydrophilic Wire Long Length Hydrophilic guidewire of .018", .025", .035", .038" in 180cm, 220cm, 260cm length	Same as NRS-248(a)
50	NRS-252	Angiography Radial Catheters 4-6F	Description Dimensions Visual Tests Surface Finish Shape Radial Curve Outer Diameter Effective Length Flat wire braiding Material Corrosion Resistance Peak Tensile Force Freedom from Leakage (Liquid and Air) Hub (Winged Polycarbonate Hub) Flow Rate

			Test for Burst Pressure
			Side Holes
			Distal Tip: Smooth & Rounded / Tapered
			Radiopaque Tip
			Sterility
			Packaging & Labelling
51	NRS-253	One loop & Triple Loop Snare	Tests for different components as per respective IS/ISO and product specifications.
52	NRS-254	PTCA Kit	Tests for different components as per respective IS/ISO and product specifications.
53	NRS-309	ANTERIOR CHAMBER IOL	Description Dimensions Mechanical Tests : Compression Force Axial Displacement in compression Optic Decentration Optic tilt Angle of Contact Compression Force Decay Loop Pull Strength Surface & Bulk Homogeneity Optical Tests: Dioptric Power MTF Test Resolution Efficiency Test Spectral Transmittance Chemical : ETO Residual Test Sterility Bacterial Endotoxin Test
54	NRS-377	PTFE COATED DIAGNOSTIC GUIDE WIRE (REGULAR LENGTH, REGULAR STIFFNESS) 0.035 inches size	Description
			Visual Test: Free from extraneous matter and surface defects
			Length
			Outside Diameter Tip Design & Configuration Coating Fixed Core / Movable core Corrosion Resistance Radio detectable Fracture Test Flexing Test Peak Tensile Force Sterility Packing & Labelling
55	NRS-381	PTFE COATED DIAGNOSTIC GUIDE WIRE – (EXCHANGE LENGTH, REGULAR STIFFNESS) 0.035inches	Same as NRS-377
56	NRS-387	Hydrophilic Diagnostic Guide Wire –	Description

		Radifocus Tarumo Type (Regular Length, Regular Stiffness) 0.032 inches	Visual Test: Free from extraneous matter and surface defects
			Length
			Outside Diameter Tip Design & Configuration Super elastic alloy core Coating Fixed Core / Movable core Corrosion Resistance Radio detectable Fracture Test Flexing Test Peak Tensile Force Sterility Packing & Labelling
57	NRS-388	HYDROPHILIC DIAGNOSTIC GUIDE WIRE – RADIFOCUS TARUMO TYPE (REGULAR LENGTH, REGULAR STIFFNESS) 0.035inches	Same as NRS-387
58	NRS-392	RADIOFOCUS MINIPLASTIC GUIDEWIRE (, REGULAR STIFFNESS) 0.035inches	Description Visual Tests Length Outside Diameter Tip Design & Configuration Super elastic alloy core Coating Fixed Core / Movable core Corrosion Resistance Radio detectable Fracture Test Flexing Test Peak Tensile Force Sterility Packing & Labelling
59	NRS-501	Angio.Kit/Ptca Kit (3 Port Many Fold With Attached Tubing One Pressure Line + Two Iv Set Connecting Tube And Two Leurlock Syringe) US FDA / CE/ APPROVED	Test for Different Components as per respective IS/ ISO and product specifications
60	NRS-532	Bone Marrow Biopsy Needle 8G 4” & 6”	Description Visual inspection: Free from moulding defects, embedded particles, other defects Components Diamond bevel tip Tapered Distal Cannula Tip Ergonometric T- Handle Triple crown cannula tip with 6 facets Corrosion Resistance Sterility Packaging & Labelling Tests to be carried as per product specification and applicable Standards/ Protocol.
61	NRS-538	Silicone foley's catheter Sizes - 14FR	Description

			Size
			Surface finish: Smooth; free from pinholes, cracks, crevices and other defects
			Colour Coding (with regard to size)
			Length of Catheter
			Wall thickness
			Catheter Tip (cushion)
			Strength of catheter
			Balloon capacity
			Balloon Security/ Safety
			Non-return valve mechanism
			Flow rate
			Fitment of drainage funnel
			Kink Stability
			Gold, Silver & Palladium alloy coating on internal and external surface
			Sterility
			Packaging & Labelling
62	NRS-542	Cutting & Coagulations device with with Wide Jaw Aperture 13mm and Cut Length 18.5mm with Shaft Rotation of 350 degrees and with One Step Sealing Mechanism.	Description Visual Test Functionality Tests Electrode Gap Test Jaw Sealer Type Jaw Force Test Hipot Test (Electrical) Jaw apperture Tissue Cut Length Shaft Rotation Test One Step Sealing Packaging Seal Integrity Labelling
63	NRS-543	Cutting &Coagulations device with with Cut Length of 14.7 mm, Seal Length of 16.5mm, Jaw Angle 28 degrees.	Description Visual Test Functionality Tests Electrode Gap Test Jaw Force Test Hipot Test (Electrical) Jaw apperture Tissue Cut Length Tissue seal length Shaft Rotation Test Packaging Seal Integrity Labelling

64	NRS-544	Cutting &Coagulations device with Tissue fusion ligature technology Laparoscopic blunt tipped vessel sealer	Description Visual Test Components Functionality Tests Electrode Gap Test Trigger Function Jaw Force & Gap Test Hipot Test / Electrical Test Jaw apperture Tissue Cut Length Shaft Rotation Test One Step Sealing Packaging Seal Integrity Labelling
65	NRS-546	Cutting &Coagulations device with Tissue fusion ligasure technology	Description Visual Test Functionality Tests Electrode Gap Test Jaw Sealer Type Jaw Force Test Hipot Test (Electrical) Jaw apperture Tissue Cut Length Shaft Rotation Test One Step Sealing Blade design & Function Packaging Seal Integrity Labelling
66	NRS-564	MULTI-VENT MASK Pediatric,	Description Components Colour Coded Diluters Locking ring to secure flow settings Adapter for high humidity entrainment Oxygen Tubing 7 ft. Tests as per product specifications and requirements and tests as per applicable standards.
67	NRS-571	Multifocal IOL	Description Multifocal IOL Dimensions of lens and haptics Haptics type Surface Quality Material Homogeneity Spectrial Transmittance Sterility Bacterial endotoxin test Sterile Disposable Injector Tests as per product specifications and requirements and tests specified under IS/ISO 11979 and other applicable standards.

68	NRS-586	Scleral fixiated intraoccular lense	Description
			Multifocal IOL
			Dimensions of lens and haptics
			Haptics type
			Surface Quality
			Material Homogeneity
			Spectrial Transmittance
			Sterility
			Bacterial endotoxin test
			Tests as per product specifications and requirements and tests specified under IS/ISO 11979 and other applicable standards.
69	S-104	ECG Electrode •Reliable trace, •High conductivity,• Easy to handle	1 Description
			Test to be performed
			2 Electrical performance
			3 Base foam Peel Adhesion
			4 Integrity of Components base foam, sensor stud, Label Stock, gel, Release Liner
			5 Liner Integrity
			6 Gel Placement on sensor
			7 Concentricity of snap/ sensor/ electrode
			8 No Foreign Mater and pouch integrity
70	NRS-23	Circular stapler 33mm with controlled tissue compression or dst technology with, longer staple leg 4.5 mm to 5.5mm , fixed or tilt top anvil, available in various shaft sizes Std. or XL for deeper access , USFDA approved	Description Visual Test : Free from scratches, burrs, cracks Dimension Shaft Size Functional Test > Firing > Fitment of Cartridge Controlled tissue Compression Anvil Package seal Packaging & Labelling Sterility
71	NRS-41	LAPROSCOPIC Linear Cutter without integrated fresh knife with 360* rotation & 0-45* articulation in both direction : for use with cartridges in sizes of 45 mm. Capable of loading all length cartridges on same gun only.	Description Visual Test : Free from scratches, burrs, cracks Dimension Functional Test * Firing * Fitment of Cartridges * Rotation * Articulation Package seal Packaging & Labelling Sterility
72	NRS-74	Speech Prosthesis for Laryngectomy (indwelling low resistance silicon voice prosthesis varied diameter with varied length should have blue teflon valve seet for primary and secondary insertion along with inserting tools and cleaning accessories) 22.5 FR (6 mm)	Description Visual Test : Free from defects Size & Dimension Material of construction Test for Valve leakage Valve opening pressure Package seal Packaging & Labelling Sterility

73	NRS-75	Speech Prosthesis for Laryngectomy (indwelling low resistance silicon voice prosthesis varied diameter with varied length should have blue teflon valve seet for primary and secondary insertion along with inserting tools and cleaning accessories) 22.5FR (8 mm)	Same as NRS-74
74	NRS-103	Urine collecting bag, disposable 2000 ml with Uroflow meter IS 8669-2	Description Components Bag volume Bag: Test for Freedom from Leakage Leakage from joints Non-return valve Strength of attachment of Inlet Tubing Bag filling rate Drainage Tap (if applicable) Uroflow meter Packaging & Labelling
75	NRS-124	LAPROSCOPIC PORT WITH TROCAR 5mm Optically guided bladeless trocar 5mm with bilateral tissue separators, optical tip to eliminate blind entry, clear ribbed cannula to enhance abdominal wall retention, recessed stopcock valve, funnel shaped housing, duckbill secondary seal, integrated universal seal that eliminates the use of reducer, 150mm length.	Description Visual Test for any defect or Non Conformities Intact Seals Dimensions Bilateral Tissue Seperators Optical Tip Clear Ribbed Cannula Recessed Stopcock Valve Integrated Universal Seal Length 150 mm Apperture of Trocar Sterility Packaging & Labelling
76	NRS-140	Patient pre operative skin prepration solution Patient pre operative skin prepration solution 25-35 ml in one step sterile applicator container for single use with 2% chlorohexdine gluconate (CHG) and 70% IPA with orange tint colour or easy visulization, US FDA Approved (As per the general specification to be used only 25-35 ml to the patient part preparation in single surgery)	Description Composition Chlorhexidine Gluconate content IPA content Colour Volume Container (as per specification) Sterility Packaging and Labelling
77	NRS-141	REM (Return Electrode Monitoring) single use, corded patient return electrodes conductive adhesive hydrogel with USFDA	Description Visual Test for any defect or Non Conformities Intact Seals Dimensions Composition Material Cord length Pad contact Functionality Packaging & Labelling

78	NRS-249	Hydrophillic Braided Sheath Hydrophilic Braided Sheath Introducer in 4F to 7F, length of 7, 11, 16, 23cm with the option of .018", .021", .025" plastic jacketed and spring coil guidewire. Should have ultra-thin wall and flat wire braiding technology to provide support and low profile.USFDA Approved	Description Hydrophilic Braided Sheath Dimensions Surface Finish Effective Length Internal Diameter Freedom from leakage from Sheath Introducer Freedom from leakage through haemostasis valve (if applicable) Compatibility with plastic jacketed and spring coil guidewire. Flat wire braiding technology Peak Tensile Force Sterility Packaging & Labelling
79	NRS-250	Femoral Sheath with Needle Femoral sheath in 5F to 8F, length of 11-23cm with puncher needle of 18g and guidewire of .035", .038". Should have rotating suture ring, snap-fit dilator to prevent slipping during insertion and holster pack. Should be available in polypropylene. USFDA Approved	Description Dimensions Surface Finish Effective Length Internal Diameter Freedom from leakage from Sheath Introducer Freedom from leakage through haemostasis valve (if applicable) Peak Tensile Force Puncture needle 18G Guidewire of .035", .038" Rotating suture ring Snap-fit dilator Sterility Packaging & Labelling Tests for components as per applicable Standards
80	NRS-327	PUR-XRO catheter 20 cm 28G / 1 FR Picc Line with Stylet, Splitting Needle with securing wings with 8 cm extension tubing (Flow rate 1 ml/ min)	Description Components Dimensions Lumen Stylet Splitting Needle with securing wings Extension tubing Catheter Material Peak Tensile Force Flow rate of Lumen Sterility Packaging & Labelling Tests as per product specifications and requirements and tests specified under IS/ISO 10555 and other applicable standards.
81	NRS-328	PUR-XRO catheter 30 cm 24G / 2 FR Picc Line with Split Cannula and 10 cm extension tubing over catheter (Flow rate 0.2 ml/ min)	Description Components Dimensions Lumen Split Cannula Extension tubing over catheter Catheter Material

			Peak Tensile Force Flow rate of Lumen Sterility Packaging & Labelling Tests as per product specifications and requirements and tests specified under IS/ISO 10555 and other applicable standards.
82	NRS-515	Venaseal Closure System for vericose veins USFDA approved N butyl based adhesive formation 50/90/105/120 cm 145 cm (3/4/6/8 F .014"/0.035" guidewire compatible)	Description Visual Test Components Adhesive : Test for viscosity, composition, setting time, Lap shear, Tensile strength, Peel adhesion strength - as per ASTM F2255-05, F2258-05, F2458-05 Dispensor Gun : Adaptor Tensile testing Catheter, Introducer, Dilator : Kink Resistance, Leak test, Tensile test - as per ISO 10555-1 and ISO 11070 Syringe : Tests as per applicable standards Dispensor Tips Guidewire : Test for Strength of union, Corrosion resistance, Wire fracture, Flexure- as per ISO 11070 Delivery System compatibility: Testing for compatibility between different components Functionality Tests / Performance Test Sterility Packaging Seal Integrity Labelling
83	NRS-547	Cutting &Coagulations device with Tissue fusion ligasure technology have vessel sealing instrument for open surgeries with reusable clamp length between 16-18cm, with 12-14 degree jaw curve. And it should have including 7mm cutting and coag with USFDA.	Description Visual Test Functionality Tests Electrode Gap Test Jaw Type Jaw Force Test Hipot Test (Electrical) Jaw apperture & curve Vessel sealing instrument Tissue Cut Length Clamp length Blade design & Function Packaging Seal Integrity Labelling
84	NRS-595	Central Line Quadro lumen with Y needle and Netinol Guidewire 8 to 8.5 fr with 15cm to 20cm catheter with Tecoflex/Polyurathane Material	Description Components Dimensions Quadro Lumen Y Needle Nitinol Guide Wire Catheter Material Peak Tensile Force

			Flow rate of each Lumen Sterility Packaging & Labelling Tests as per product specifications and requirements and tests specified under IS/ISO 10555 and other applicable standards.
85	NRS-609	2 PCS FLAT BASE OSTOMY BODY FIT BAG 60 MM 2-piece system base plate with body fit additional elastic adhesive technology (Elastic modulus-0.18 N/mm), With 2 to 4 ears belt lock. Colostomy Bag, consists one barrier foil and a Oecotex certified water repellent textile material .Triple layer filter with full circle pre filter and drainage locking system. Window on bag for inspection 60MM . With nursing care services and trained hospital staff as well stomach care clinic.	Description Visual Test 2-piece system Base Type Components Dimensions 2-4 ears belt lock Material of construction of ostomy bag Tripple layer system Drainage locking system Inspection window on Bag Test for freedom from leakage Test for Burst Strength Sterility Packaging & Labelling Tests as per product specifications and requirements and tests specified under ISO 8670-2,3 and other applicable standards.
86	NRS-610	2 PCS FLAT BASE OSTOMY BODY FIT BAG 70 MM 2-piece system base plate with body fit additional elastic adhesive technology (Elastic modulus-0.18 N/mm), With 2 to 4 ears belt lock. Colostomy Bag, consists one barrier foil and a Oecotex certified water repellent textile material .Triple layer filter with full circle pre filter and drainage locking system. one side transparent for inspection. 70MM. With nursing care services and trained hospital staff as well stomach care clinic	Same as NRS-609
87	NRS-611	2 PCS CONVEX BASE OSTOMY BODY FIT BAG 60 MM Two-piece system 6 mm aperture convex with integrated flex line base plate. body fit additional elastic adhesive technology (Elastic modulus-0.18 N/mm), With 2 to 4 ears belt lock.Colostomy Bag, consists one barrier foil and a Oecotex certified water repellent textile material. Triple layer filter with full circle pre filter and drainage locking system. . Window on bag for inspection 60MM.	Same as NRS-609

88	NRS-626	(a) Polysiloxane or Silicone Gel sheet for scar management. size 10 * 10 cm (b) Polysiloxane or Silicone Gel sheet for scar management. size 5 * 5 cm	Description Dimension Thickness Moisture/ Vapour transmission rate Tack after washing Microbiological Tests Total microbial count Total yeast and mould count S. aureus P. aeruginosa Clostridium sporogenes
89	NRS-627	Triple layered antimicrobial form dressing for burn wounds with silver sulphate, silver content 1.2mg/cm2 with active release of silver upto 7 days with soft silicon atraumatic wound contact layer for painless dressing change. Product should be CE/USFDA certified Size 20x20 cm +15% deviation in size will be acceptable.	Description Visual Test Size Foam Dressing Silicon wound contact layer Silver sulphate content Silver content 1.2mg/ cm2 (active release of silver upto 7 days) Hydrocolloid Matrix Antimicrobial Waterproofness of outer film Capacity of Absorption Sterility Packaging Labelling
90	NRS-629	Dressing with native collagen-elastin / biodegradable matrix, flexible, conformable at anatomical area, easy to use, apply & handle. Size more than 70x50mm & 2mm in thickness. CE/USFDA certified.	Description Visual Test Size Thickness Native Collagen elastin Matrix Flexibility Conformability at anatomical areas Sterility Packaging Labelling
91	NRS-633 a	Sulu Stepped Cartridges for variable tissue application , fixed anvil , different leg length staples in same cartridge , inbuilt knife ,size 60 mm inner to outer side 3.0,3.5 and 4.0 mm , purple colour code, USFDA Approved, 8mm	Same as 633 b

92	NRS-633 b	Sulu Stepped Cartridges for variable tissue application , fixed anvil , different leg length staples in same cartridge , inbuilt knife ,size 60 mm inner to outer side 3.0,3.5 and 4.0 mm , purple colour code, USFDA Approved 10mm	Description Visual Test : Free from scratches, burrs, cracks Number of staple rows Dimension Staple length Staple height Fixed Anvil Inbuilt knife Functional Test Fitment in Stapler/ Cutter Firing Colour code Package seal Packaging & Labelling Sterility
93	NRS-686	Nasal Haemostatic sponge pack With out Airway 8 cm	Description Visual Test Size Material Sterility Packaging Labelling
94	NRS-687	Nasal Haemostatic sponge pack With out Airway 10 cm	same as 686
95	NRS-688	Nasal Haemostatic sponge Pack (With Airway) 8 cm	Description Visual Test Size Material of construction Airway Sterility Packaging Labelling
96	NRS-718	Flexometlic Tube 3-8.5 with stylet Reinforce ET Tube with wiring from tip to end it should be approved by *US FDA	Tests as per product specifications and requirements and tests specified under ISO 5361:2023 and other applicable standards.
97	NRS-721	Disposable transducers for invasive pressure monitoring· Should be compatible with available system in Cath Lab and ICCU at SMSH· Should meet highest medical industrial standards· Quality certification should be provided form authorized agencies.US FDA + CE/ DGCI APPROVED· (IABP – Data Scope & Cath Lab transducer)	Tests as per product specifications and requirements and tests specified under IEC 60601-2-34 ; ANSI/AAMI BP22:1994 and other applicable standards.
98	NRS-732	Dialyzer size 1.3 SQM Dialyzer with blood tubing set Dialyzer should be synthetic Membrane (Poly sulfon/ polyethersulfon) Blood tubing set must be same company.	Dialyzer : Description Surface Finish Components and Assembly Fitment of Components Dimension Test for Structural Integrity Blood Compartment Integrity

			Membrane (Filter) Integrity Membrane material Performance indicators Bacterial Endotoxin Test Sterility Packaging & Labelling Tests for Blood Tubing: Description Surface Finish Components and Assembly Leakage from joints under pressure Test for blockage Clamp Functionality Flow rate Kink resistance Separation force test at different connections Effective length I.D. & O.D. Bacterial Endotoxin Test Sterility Tests as per product specifications and requirements and tests specified under applicable standards.
99	NRS-733	Dialyzer size 1.4 SQM with blood tubing set. Dialyzer should be synthetic membrane (Poly sulfon/ polyethersulfon). Blood tubing must be of same company.	Same as NRS-732
100	NRS-734	Dialyzer size 1.6 SQM with blood tubing set. Dialyzer should be synthetic membrane (Poly sulfon/ polyethersulfon)	Same as NRS-732
101	NRS-735	Dialyzer size 1.8 SQM with blood tubing set. Dialyzer should be synthetic membrane (Poly sulfon/ polyethersulfon)	Same as NRS-732
102	NRS-736	Padiatric Dialyzer size 0 .6 SQM Padiatric Dialyzer (Dialyzer should be synthetic Membrane Polysulfon/polyethersulfon) Other Product required for Hemodialysis 1. Blood Tubing 2. AV Fistula Needle 16G/17 G 3. Transducer Protector	Same as NRS-732
103	NRS-737	Padiatric Dialyzer size 0.8 SQM Padiatric Dialyzer (Dialyzer should be synthetic Membrane Polysulfon/polyethersulfon) Other Product required for Hemodialysis 1. Blood Tubing 2. AV Fistula Needle 16G/17 G 3. Transducer Protector	Same as NRS-732

ANNEXURE –VIII
Ref: Clause no. 3 (r)

To fill up the remark column of the enclosed Performa to access the existing facilities of your laboratories

A - General requirements and premises

S.N.	Details of the requirement	Remark
1	For Laboratory management a qualified individual known as quality manager or technical manager is appointment.	
2	The Laboratory is designed, contracted and maintained to prevent entry of insects and rodents besides cross contaminations ;	
3	Interior surface (wall, floor, and ceilings) are smooth and free from cracks, and permit easy cleaning and disinfection ;	
4	Adequate provision for space and equipment for carrying out necessary test is provided & also unities like water, power and gas ;	
5	Air ventilations system is provide to ensure dust free environments	
6	The laboratories provided with adequate lighting and ventilation, air conditioning to maintain satisfactory temperature and relative humidity	
7	The faculties of drainage system and to prevent water logging in the laboratory	
8	Tables tops is made of with acid, alkali and solvent resistant material	
9	Adequate space with proper storage conditions in the laboratory shall be provided for keeping Reference and working standards	
10	The air circulation is maintained in the area where sterility test is carried out as per Schedule M.	

B- Personal & Equipment

S.N.	Details of the requirement	Remark
1	Staff in the laboratory shall possess necessary qualification, proper training and shall have Adequate, experience for the assigned duties.	
2	A training record of all the personal shall be maintained.	
3	Head of the laboratory must be high professional standing with experience in drug analysis and laboratories management	
4	The analytical instrument shall be housed in the dust-free environment and with controlled conditions of temperature and humidity	
5	A progress register for non functional equipments and action for procurement of spares and accessories, monitoring there of, shall be maintained	
6	A standard operating procedure for preventive maintenance of machine or equipment or apparatus shall be prepared by the laboratory	
7	Equipments such as burette, pipettes, volumetric flasks, weight boxes, thermometers etc. shall be thoroughly checked for accuracy for calibration before acceptance of use	
8	Equipments, instruments giving anomalous results or defective must be labeled as out of order	
9	Autoclaves must meet the requirements described for operations, safety and validation procedures	

S.N.	Details of the requirement	Remark
10	Work involving the evolution of harmful and obnoxious vapors shall be carried out in a fume cupboard	

_Chemicals and Reagents, Good housekeeping and safety

S.N.	Details of the requirement	Remark
1	All reagents and solutions in the laboratory shall be property identified with a label.	
2	A standardization register shall be maintained, with its raw date and SOP for preparation and standardization on stock solutions, standard solutions and volumetric solutions.	
3	Containers of stock solutions and of standard solutions shall bear the details.	
4	The storage and handling of chemicals and reagents shall be done in a manner considering the physicochemical properties substances and the hazard involved in their use.	
5	General and specific written down instructions for safety shall be circulated to each staff member.	
6	SOP for safety, house-keeping and loss prevention.	
7	Drinking, eating and smoking shall not be permitted in the laboratories.	
8	Staff must wear laboratory coats or other protective clothing including gloves and face masks and eye protection wherever required	
9	The laboratories shall have adequate firs aid kit and fire fighting equipments.	
10	Operators carrying out sterility tests shall wear sterilized garments including headgear, face masks and shoes.	
11	The staff must be educated in the first aid techniques, emergency care and use of antidotes.	
12	Safety rules in handling cylinders of compressed gases must be observed and staff must be familiar with relevant colors identification codes ;	
13	Protective Precautions - 1- water showered 2- Rubber suction bulbs must be used on manual and siphons ; 3- Warnings, precautions and written Instructions violent, uncontrollable or reactions. 4- Appropriate facilities for the collection, storage and disposal of wasters. 5- Safe disposal of corrosive or dangerous products by neutralization or deactivation. 6- Safety precautions to be adopted while handling potassium cyanide and bromide ; 7- SOP for handing, collection, disposal of chemical and biological wastes.	

Maintenance, calibration, and validation of equipment & Reference materials : Microbiological Cultures :

S.N.	Details of the requirement	Remark
1	All equipments, instruments and other devices used in the laboratory shall use appropriate methods and procedures for all tests or calibrations and they shall be regularly Calibrated and validated.	
2	For most of the equipments and instruments, SOP for calibration and calibration schedule be the laboratory and a logbook shall also be prepared by each laboratory for proper documentation of calibrations results.	
3	Reference material shall be traceable to agency authorized by Government of India or any other International body.	
4	The laboratory shall prepare working standard by comparing with the reference standards and shall be routinely checked for their purity.	
5	Whenever, any new reference material is received by the laboratory following details are to be written - a- Source of supply ; b- Code number of the reference material ; c- Date of receipt ; d- Batch number or identification number of the supplying agency ; e- Details like assay value, water content or information provided ; f- Storage condition of the material ; g- Date of expiry, if any and date of manufacturing if possible.	
6	SOP for maintenance of microbial culture and sub-culture must be prepared by the laboratories ;	

Quality system : & internal quality audits, management review :

S.N.	Details of the requirement	Remark
1	The measurements and calibrations shall fully conform to the compendia requirements and the method demonstrably based on validation protocols are followed.	
2	Remedial action o the observations by internal and external audits are taken appropriately	
3	Documented quality policy for the organization.	
4	Internal audits are done to assure the integrity of the analysis ad such audits shall be conducted periodically	
5	Each activity is audited at least once in a year.	
6	The quality manager shall maintain all the records of the analysis being conducted which includes test system, the type of analysis , date on which analysis is done	
7	Review yearly 1- Report or input	

S.N.	Details of the requirement	Remark
	2- Matter arising from previous reviews ; 3- Report of external audits, if any ; 4- Surveillance report, if any ; 5- Result of proficiency testing ; 6- Complaints or feedback received from users 7- Details of in-house quality control checks ; 8- Need of amendment of the quality system and documentation ; 9- Introduction training of new staff.	

Standard operating Procedures

S.N.	Details of the requirement	Remark
1	Shall be written in a chronological order listing different steps leading to an analysis of drugs or calibration of an instruments ;	
2	Shall have SOP manuals and have periodic Review.	
3	Standard Operation Procedures for the followings are required (i) Sample handling and accountability ; (ii) Receipt identification, storage, mixing and method sampling of the test and control articles ; (iii) Record keeping, reporting, storage and retrieval of data ; (iv) Coding of different studies, handling of data including use of computerized data system : (v) Operation of technical audit personnel in performing and reporting audits, inspections and final report reviews ; (vi) Routing inspection of cleaning maintenance, testing, calibration and standardization of instruments ; (vii) Action to be taken in respect of equipment failure ; (viii) Analytical data methods (ix) Health and safety protection ; (x) Date handling and storage retrieval ; (xi) Health and safety protection ; (xii) Animal room preparations ; (xiii) Animal care ; (xiv) Storage and maintenance of microbial cultures ; (xv) Maintenance of sterility room (i.e. constant maintenance and monitoring of Aseptic condition room) ; (xvi) Use and storage of reference standards ; (xvii) Procurement of stores and equipment ; (xviii) Monitoring of testing of samples ; (xix) Method of retention of unexpended samples, their location, maintenance and disposal ; (xx) Document control ;	

S.N.	Details of the requirement	Remark
	(xxi) Redressal of technical complaints ; (xxii) House- keeping (xxiii) Corrective and preventive action ; (xxv) Calibration manual. (xxvi) Training manual.	
4	Protocols and specification archive :- List of all the pharmacopeias a file on patent and proprietary medicines (non-Pharmacopeia) test methods to specification prepared and validated by the manufacturer. The test methods shall be submitted to the concerned Drug Control Authority.	
5	Raw data - Date integrity and security shall be maintained Original entry must be saved and the system shall trail for all data.	
6	Storage and archival ; The residual sample shall be retained in proper storage condition for a period of one year after the final report.	
7	The laboratory must establish and maintain procedures for the identification collection, indexing, retrieval, storage, maintenance, and Disposal of all quality documents.	
8	All the raw date, documentation, SOP, protocols and final reports are the be retained and there shall be archives of orderly storage and expeditious retrieval of all raw data, documentation, protocols, interim and final report.	
9	The condition under which the original documents are stored must ensure their security and confidentiality.	
10	Raw data on thermal paper might fad away with time ; therefore, a photocopy of the thermal paper shall be retained in the archive.	

Above mentioned information correct as per our record and if found incorrect, RMSC may take action against our firm and reject our bid.

Signature:
Name of the Lab:
Date:
Official Seal: