Ref. No.: F.02(139)/RMSCL/LAB EMPANELMENT(S&S)/NRD/NIB-08//2023/1648 Dated:-18.04.2023

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 (Ending on 31.03.2025)

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LAST DATE OF SUBMISSION OF ONLINE BIDS	**09.05.2023 at 6.00PM**
DATE AND TIME OF OPENING OF ONLINE TECHNICAL BIDS	**10.05.2023 at 11.00 AM**

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
(A Govt. of Rajasthan Undertaking)
Gandhi Block, SwasthyaBhawan, 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(139)/RMSCL/LAB EMPANELMENT(S&S)/NRD/NIB-08/2023/1648 Dated:-18.04.2023

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	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	ReF : .: F.02(139)/RMSCL/LAB EMPANELMENT(S&S)/NIB-08/NRD/2023/ Dated :		**09.05.2023 up to 6.00PM**

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 31.03.2025)

Bid Reference	:	REF : F.02(139)/RMSCL/LAB EMPANELMENT(S&S)/NIB-08/NRD/2023/1648 Dated:- 18.04.2023
Date and time for downloading bid document	:	18.04.2023 from 6.00 PM
Pre- bid conference	:	25.04.2023 at 11.00 A.M. (RMSC Board Room)
Last date and time of submission of online bids	:	09.05.2023 up to 6.00 PM
Date and time of opening of Online technical bids	:	10.05.2023 at 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. 1770/- (including GST @ 18%)**
Empanelment Fee	:	**Rs. 5900/- (including GST @ 18%)**
Estimated Cost	:	**Rs. 80 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 31.03.2025)

"CONFIDENTIALITY IS THE ESSENCE OF THIS BID"

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 09.05.2023** 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 31.03.2025**) 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 SecurityDeposit**
- Processing fee of Rs. 1770 (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 Punjab National Bank Account no. 2246002100024414 & IFSC Code no. PUNB0224600 throughout country upto 09.05.2023 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 **09.05.2023** 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 SecurityDeposit. In the absence of Bid document fees and processing fees and **Bid SecurityDeposit** 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.

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.

(3) The laboratory should have an average annual turnover of **not** less than **Rs. 1 Crore** for past preceding three years (**2018-19, 2019-20 & 2020-21 or 2019-20, 2020-21 & 2021-22**).(ANEXURE-II)

(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 – VIII</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 VIII to be submitted with technical bid.

NOTE: - Bidders have to mentioned/quote all the test parameters compulsorily in annexure-VIII, 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 SecurityDeposit / 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 SecurityDeposit) 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 proforma as given in Annexure III.

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

g. Non- Conviction Certificate issued by by the Licensing Authority.

h. Annual turnover statement for last 3 year i.e **2018-19, 2019-20 & 2020-21 or 2019-20, 2020-21 & 2021-22** (ANEXURE-II) certified by the practicing Chartered Accountant.

i. Copies of the Balance Sheet and Profit and Loss Account for three years i.e **2018-19, 2019-20 & 2020-21 or 2019-20, 2020-21 & 2021-22** 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 proforma 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. Documentary evidence for the constitution of the company / concern.

o. 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.

p. Bidders has to fill up the checklist Anne – IX. the infrastructure and testing facilities available in the lab.

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 Securityshall be Rs. 20,000/- paid through separate prescribed challan (format enclosed in Annexure-I) in any branch of the Punjab National Bank Account no. 2246002100024414 & IFSC Code no. PUNB0224600 throughout country up to **09.05.2023** or through D.D. / bankers cheque in favor of M.D. RMSCL physically in the office of RMSCL on or before **09.05.2023** upto 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 analysed 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 GSTes.
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 31.03.2025. If required period of contract can be extended upto 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/ammendmends, (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 apply when only specific testing is called for/desired on any particular sample. If IS/ISO Or pharmacopeial 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 Securityshall 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 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 authorised 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 a 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 behaviour 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-in0chage/ 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 Copy

punjab national bank

DIST. NO.

Branch

Institute Name: Rajasthan Medical Services Corporation, Jaipur

Institute ID: RMSCJ - A/c No. 2246002100024414

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

Customer Copy

punjab national bank

DIST. NO.

Branch

Institute Name: Rajasthan Medical Services Corporation, Jaipur

Institute ID: RMSCJ - A/c No. 2246002100024414

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

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 (Rs)
1	2018-19	
2	2019-20	
3	2020-21	
Total		**Rs.** **Lakhs**
Average turnover per annual		**Rs.** **Lakhs**

OR

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

Date:

Seal:

Siganture of Auditor/
Chartered Accountant
(Name in Capital)

UDIN NO.

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 Analysed No. of Samples Analysed during **(2018-19, 2019-20 & 2020-21 or 2019-20, 2020-21 & 2021-22)**

01. Surgicals (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:

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 31.03.2025) 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(139)/RMSCL/LAB EMPANELMENT(S&S)/NIB-08/NRD/2023/1648 Dated:-18.04.2023

   For the empanelment of analytical testing laboratories for the test and analysis of SURGICAL &SUTURES/MEDICAL DEVICES (Ending on 31.03.2025) 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 VIII and quoted for products as given below:-

Sr No.	**Quoted item Code No. (as per mention in Annexure-VIII)**
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 GSTes 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. l/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 ……

(Affidavit Page2)

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
Ref: Clause no. 3 (a),7(1)

SUTURES LIST

S.No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
1	NRR-1	Braided E Caprolactone Coated Lactomer 1, 90cm GS-25,37-40MM1/2 CIRCLE TAPER POINT	12 Foils	Class C
2	NRR-2	Braided E Caprolactone Coated Lactomer 2-0 90cm GS-25,3OMM1/2 CIRCLE TAPER POINT	12 Foils	Class C
3	NRR-3	Braided E Caprolactone Coated Lactomer 1 90cm Gs-25,37-40MM1/2 CIRCLE REVERSE CUTTING	12 Foils	Class C
4	NRR-4	Polyglactin910 (90% Glycolide & 10 % Lactide) Coated With 370 Polyglactin & Calcium Stearate, Impregnated With 97-103% Pure As Per USP Specifition, Purest Form Of Triclosan,40mm Needle, Size 1, 1/2 Circle Taper Point, 90 Cm	12 Foils	Class C
5	NRR-5	Braided E-Caprolactone Coated Lactomer 3-0 75CM C-14 , UNDYED 24MM 3/8 Circle Reverse Cutting	12 Foils	Class C
6	NRR-6	Polyglactin910 (90% Glycolide & 10 % Lactide) Coated With 370 Polyglactin & Calcium Stearate, Impregnated With 97-103% Pure As Per USP Specifition, Purest Form Of Triclosan,30mm Needle, Size 2-0, 1/2 Circle Taper Point, 90 Cm	12 Foils	Class C
7	NRR-7	Polyglactin910 (90% Glycolide & 10 % Lactide) Coated With 370 Polyglactin & Calcium Stearate, Impregnated With 97-103% Pure As Per USP Specifition, Purest Form Of Triclosan,40mm Needle, Size 1, 1/2 Circle Reverse Cutting OS Needle, 90 Cm	12 Foils	Class C
8	NRR-8	Braided E-Caprolactone Coated Lactomer 0 90CM GS-24 , VIOLET 40MM 1/2 Circle Taper Point	12 Foils	Class C
9	NRR-9	Polyglactin910 (90% Glycolide & 10 % Lactide) Coated With 370 Polyglactin & Calcium Stearate, Impregnated With 97-103% Pure As Per USP Specifition, Purest Form Of Triclosan,20mm Needle, Size 3-0, 1/2 Circle Taper Point, 70 Cm	12 Foils	Class C
10	NRR-10	Braided E-Caprolactone Coated Lactomer 1-0 90CM GS-25 , UNDYED 37-40MM 1/2 Circle Reverse Cutting	12 Foils	Class C
11	NRR-11	Polyglactin 910 Violet Braided, 1, 35 CM 1/2 Circle Reverse Cutting (Heavy) 23 MM -25 MM Needle	12 Foils	Class C
12	NRR-12	Polyglactin 5-0 RB Oval ½ Circle 16 Mm 45 Cm	12 Foils	Class C
13	NRR-13	Polyglactin 5-0 CC 3/8 Circle 16 Mm 45 Cm	12 Foils	Class C
14	NRR-15	Polyglactin910 (90% Glycolide & 10 % Lactide) Coated With 370 Polyglactin & Calcium Stearate, Impregnated With 97-103% Pure MP, Purest Form Of Triclosan, 26mm Needle, Size 2-0, 3/8 Circle Cutting, 90 Cm	12 Foils	Class C
15	NRR-18	Absorbable Surgical Suture Sterilized Surgical Needled Suture Monofilament Polydioxanone, Violet 1/2 Circle Taper Point RB-2, Double Needle, 13 Mm Needle, Length 70cm SIZE 5-0	12 Foils	Class C
16	NRR-19	Absorbable Surgical Suture Sterilized Surgical Needled Suture Monofilament Polydioxanone, Violet 3/8 Circle Taper Point, BB SGLE ARMED Needle 17 Mm Needle, Length 70cm SIZE 5-0	12 Foils	Class C
17	NRR-22	Absorbable Surgical Suture Sterilized Surgical DOUBLE ARMED Needled Suture Monofilament Polydiaxanone Violet 6-0 RB 17 MM NEEDLE LENGTH 90 CM	12 Foils	Class C

S.No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
18	NRR-23	Absorbable Surgical Suture Sterilized Surgical DOUBLE ARMED Needled Suture Monofilament Polydiaxanone Violet 6-0 RB 11 MM NEEDLE LENGTH 90 CM	12 Foils	Class C
19	NRR-24	Absorbable Surgical Suture Sterilized Surgical DOUBLE ARMED Needled Suture Monofilament Polydiaxanone Violet 5-0 RB 11 MM NEEDLE LENGTH 90 CM	12 Foils	Class C
20	NRR-25	Absorbable Surgical Suture Sterilized Surgical SINGLE ARMED Needled Suture Monofilament Polydiaxanone Violet 5-0 RB 17 MM NEEDLE LENGTH 90 CM	12 Foils	Class C
21	NRR-26	Monofilament Polyglyconate 1 150cm Gs-25 Loop, Green 48mm 1/2 Circle Taper Point	12 Foils	Class C
22	NRR-27	Monofilament Polyglyconate 2-0, 75cm GREEN 26-30MM 1/2 Circle Taper Point	12 Foils	Class C
23	NRR-28	Monofilament Polyglyconate 3-0, 75cm GREEN 20-26MM 1/2 Circle Taper Point	12 Foils	Class C
24	NRR-29	Monofilament Polyglyconate 4-0, 75cm GREEN 17-20MM 1/2 Circle Taper Point	12 Foils	Class C
25	NRR-30	Monofilament Synthetic Absorbable Suture Polydioxanone - Violet EP 3-0,70 Cm,1/2 Circle R.B.,20 Mm	12 Foils	Class C
26	NRR-31	Monofilament Synthetic Absorbable Suture Polydioxanone - Violet EP 4-0,70 Cm,1/2 Circle R.B.,20 Mm	12 Foils	Class C
27	NRR-32	Monofilament Synthetic Absorbable Suture Polydioxanone - Violet EP 5-0,70 Cm,1/2 Circle R.B.,13 Mm	12 Foils	Class C
28	NRR-33	Monofilament Glycomer 1 90cm Gs-21 , Volet 37mm 1/2 Crcle Taper Pont	12 Foils	Class C
29	NRR-34	Monofilament Glycomer 2-0 90cm Gs-21 , Volet 37mm 1/2 Crcle Taper Pont	12 Foils	Class C
30	NRR-35	Non Absorbable Surgical Suture, Sterilized Surical Needled BLACK BRAIDED SILK WITH NEEDLE 1/2 Circle Round Bodied 30 Mm Needle , Length 70 Cm Size 2-0	12 Foils	Class C
31	NRR-36	Braided Coated Non Absorbable Suture USP 1-0 75 Cm X 2	12 Foils	Class C
32	NRR-37	Braided Coated Non Absorbable Suture USP 2-0 75 Cm X 2	12 Foils	Class C
33	NRR-38	Braided Coated Non Absorbable Suture USP 3-0 75 Cm X 2	12 Foils	Class C
34	NRR-39	Silk Reel 4-0	12 Foils	Class C
35	NRR-44	Braided Polyester Caoted With Silicon 2, 26MM 1/2 Circle RC 75cm	12 Foils	Class C
36	NRR-45	Braided Polyester Caoted With Silicon 5, 55MM 1/2 Circle RC 75cm	12 Foils	Class C
37	NRR-54	Polypropylene Blue Monofilament, 2-0, 90 CM 1/2 Circle Round Body Double Needle 26 MM	12 Foils	Class C
38	NRR-55	POLYPROPYLENE BLUE MONOFILAMENT USP 3/0,2,90 Cm,1/2 Circle Taper Point (Double Armed),26 Mm	12 Foils	Class C
39	NRR-56	Polypropylene Blue Monofilament, 4-0, 75 Cm 1/2 Circle Round Body Double Needle 17 Mm	12 Foils	Class C
40	NRR-57	POLYPROPYLENE BLUE MONOFILAMENT USP 5/0,1,90 Cm,1/2 Circle Taper Point (Double Armed),18 Mm	12 Foils	Class C
41	NRR-58	Polypropylene Blue Monofilament, 6-0, 75 CM 3/8 Circle Round Body (380 Microns) Double Needle (**Cutting)** 13 MM	12 Foils	Class C

S.No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
42	NRR-59	Non Absorbable Polypropylene Surgical Sutures Size:7-0,3/8 Circle C1 Taper Point CV Needle Made Of Tungsten - Rhenium Alloy And Finished With Multilayer Silicon Coating Double Armed,8 Mm,60 Cm	6 Foils	Class C
43	NRR-60	Monofilament Polybuetester Coated With Polytribiolate 6-0 75CM 2XCV-1X36 , BLUE 9MM 3/8 Circle Taper Point	6 Foils	Class C
44	NRR-61	Monofilament Polybuetester Coated With Polytribiolate 4-0 90CM 2XCV-23X36 , BLUE 17MM 1/2 Circle Taper Point	12 Foils	Class C
45	NRR-62	Monofilament Polybuetester Coated With Polytribiolate 7-0 60CM 2XMV-175-8 , BLUE 8MM 3/8 Circle Taper Point	12 Foils	Class C
46	NRR-63	Monofilament Polybuetester Coated With Polytribiolate 2-0 90CM 2XV-20X36 , BLUE 26MM 1/2 Circle Taper Point	12 Foils	Class C
47	NRR-64	Monofilament Polybuetester Coated With Polytribiolate 3-0 90CM 2XV-20X36 , BLUE 26MM 1/2 Circle Taper Point	12 Foils	Class C
48	NRR-65	Non-Absorbable Synthetic Unidirectional Dual Cut Angle Barb With Welded **Loop Or Tab** End Made Up With Polybeutester Size 1, 37mm, 30cm, 1/2 Circle, TP	12 Foils	Class C
49	NRR-66	Synthetic Absorbable Wound Closure Device With Dual Cut Barb With Velded **Loop Or Tab** On End Madeup With Polybeutester Blue Size 2-0, 1/2 Circle, 37mm, 30cm TP,	36 Foils	Class C
50	NRR-67	Absorbable Synthetic Unidirectional Dual Cut Angle Barbed With Welded **Loop Or Tab** End Made Up With Polyglyconate 2-0 26-30 Mm 30 Cm 1/2 Circle Taper Point	12 Foils	Class C
51	NRR-68	Synthetic Absorbable Wound Closure Device With Dual Cut Barb With Velded **Loop Or Tab** On End Madeup With Polyglyconate Green Size 1-0, 1/2 Circle, 37mm, 30cm TP	12 Foils	Class C
52	NRR-69	Synthetic Absorbable Wound Closure Device With Dual Cut Barb With Velded **Loop Or Tab** On End Madeup With Polyglyconate Green Size 2-0, 1/2 Circle, 26mm, 30cm TP	12 Foils	Class C
53	NRR-70	Synthetic Absorbable Wound Closure Device With Dual Cut Barb With Velded **Loop Or Tab** On End Madeup With Polyglyconate Green Size 3-0, 1/2 Circle, 26mm, 30cm TP	12 Foils	Class C
54	NRR-71	Synthetic Absorbable Wound Closure Device With Dual Cut Barb With Velded Loop On End Madeup With Glycomer Blue Size 2-0, 1/2 Circle, 24mm, 30-45cm RC	12 Foils	Class C
55	NRR-73	Polyester Ethylene Terephthalate Nonabsorbable Surgical Suture Polyester Suture Is A Nonabsorbable, Braided, Sterile, Surgical Suture Composed Of Poly (Ethylene Terephthalate.) It Is Prepared From Fibers Of High Molecular Weight, Long-Chain, Linear Polyesters 1 /2 Circle Tapercut 2 X V-5 Double Needle 26 Mm 90 Cm Green Color Size 2-0	12 Foils	Class C
56	NRR-74	Laproscopic Knotless PGA -PCL Bidirectional Taper Point Surgical Suture Self Fixation Device With Autolock Mechanism Made Up Of PGA -PCL Bidirectional Taper Point 17 Mm & 32cm	12 Foils	Class C
57	NRR-79	Braided Coated Non Absorbable Suture Natural Silk - Black Dyed USP 1-0,90 Cm,1/2 Circle R.B.,30 Mm	12 Foils	Class C
58	NRR-80	Non-Absorbable Surgical Suture Black Braided Silk 1-0 RC 3/8 Circle 45 Mm 76 Cm	12 Foils	Class C
59	NRR-81	Non-Absorbable Surgical Suture Black Braided Silk 5-0 RC 3/8 Circle 12 Mm 76 Cm	12 Foils	Class C
60	NRR-82	Braided Coated Non Absorbable Suture Natural Silk - Black Dyed USP 5-0,76 Cm,3/8 Circle R.B,12 Mm	12 Foils	Class C
61	NRR-83	Non-Absorbable Surgical Suture Black Braided Silk 6-0 RC MP 3/8 Circle 8 Mm	12 Foils	Class C

S.No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
62	NRR-85	Braided Coated Polyglactin Absorbable Suture Polyglactin 910 -Undyed 2-0, 1/2 Circle Taperpoint, 36 Mm,100 Cm	12 Foils	Class C
63	NRR-86	Absorbable Surgical Suture (Synthetic)Coated Polyglactin/PGA 910 Voilet 6-0 RB Micro Point ¼ Circle 8 Mm 45 Cm '2670'	12 Foils	Class C
64	NRR-87	Absorbable Surgical Suture (Synthetic)Coated Polyglactin/PGA 910 Voilet 4-0 CC 3/8 Circle 16 Mm 45 Cm '2442'	12 Foils	Class C
65	NRR-88	Absorbable Surgical Suture (Synthetic)Coated Polyglactin/PGA 910 Voilet 3-0 CC 3/8 Circle 16 Mm 45 Cm '2442'	12 Foils	Class C
66	NRR-90	Absorbable Surgical Suture (Synthetic)Coated Polyglactin/PGA 910 Voilet 5-0 CC 3/8 Circle 16 Mm 45 Cm '2442'	12 Foils	Class C
67	NRR-91	Absorbable Surgical Suture (Synthetic)Coated Polyglactin/PGA 910 Voilet 5-0 RB Oval 1/2 Circle 16 Mm 45 Cm	12 Foils	Class C
68	NRR-95	Non Absorbale Surgical Suture Sterlised Surgical Needle Suture Polyamide Mono Filament Black (Nylon) 3/8 Conventional Cutting Needle 26mm Length 70cm3-0	12 Foils	Class C
69	NRR-96	Non Absorbable Surgical Suture Sterilized Surgical Needle Suture Polyamide Mono Filament Black (Nylon) 3/8 Conventional Cutting Needle 16mm Length 70cm4-0	12 Foils	Class C
70	NRR-97	Non Absorbale Surgical Suture Sterlised Surgical Needle Suture Polyamide Mono Filament Black (Nylon) 3/8 Conventional Cutting Needle **16mm** Length 70cm 5-0	12 Foils	Class C
71	NRR-98	Non Absorbable Polypropylene Surgical Sutures Size:6-0,3/8 Circle 175-6 Taper Point /RC BV Needle Made Of Tungsten - Rhenium Alloy And Finished With Multilayer Silicon Coating Double Armed,9.3 Mm,60 Cm 13 Mm	12 Foils	Class C
72	NRR-99	Non Absorbable Polypropylene Surgical Sutures Size:7-0,Compound Curve (1/2 & 3/8 Circle) Circle 175-6 Taper Point Blackmatte Needle Made Of Tungsten - Rhenium Alloy And Finished With Multilayer Silicon Coating Double Armed,9.3 Mm,60 Cm	12 Foils	Class C
73	NRR-100	Monofilament Synthetic Absorbable Suture Poliglecaprone 25 - Undyed EP 3-0,70 Cm,1/2 Circle Oval R.B. J.B. Needle,26 Mm	12 Foils	Class C
74	NRR-103	Braided Coated Polyglactin Absorbable Suture Polyglactin 910 -Undyed 3-0, 3/8 Circle Reverse Cutting,PS Prime 24 Mm,75 Cm	12 Foils	Class C

ANNEXURE VIII

Clause 2(8)

NOTE:- Bidders have to mentioned/QUOTE all the test parameters compulsorily in column no.6 (Agree to perform test parameters), If any bidder does not mention/QUOTE any parameter/parameters as narrated in column no. 5, then the bid shall be treated as non-responsive for that particular item.

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
1	2	3	4		5	6
1	All items including in Annexure VII	Sutures (Sterilized Surgical Needled Sutures) USP / BP		A	**Physical**	
				1	Description	
				2	Average Length	
				3	Average Diameter	
				4	Tensile Strength (for USP/Average knot pull tensile strength (BP))	
				5	Needle Attachment	
				6	Test of Barb (For suture with barb)	
				B	**Tests for Needle**	
				1	Needle description	
				2	Size	
				3	Shape	
				4	Dimension	
				5	Flexibility	
				6	Sharpness	
				7	Smoothness and finish	
				8	Test for metal-Tungsten Rhenium Alloy (Applicable for needle made of such metal)	
				C	**Chemical Tests**	
				1	Identification test for suture material	
				2	Extractable Colour (if suture is dyed)	
				3	Soluble chromium compounds (only for chromium catgut)	
				4	Anti-bacterial chemical content (only for antibacterial coated sutures)	
				5	Corrosion resistance test for needle	
				D	**Biological Test**	
				1	Sterility	

NOTE:-

*** The parameters of testing of sutures will be as per the respective pharmacopoeia/BIS/ISO.**

*** The above tests are minimum tests to be performed.**

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

ANNEXURE –IX
Ref: Clause no. 3 (p)

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	
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 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	

S.N.	Details of the requirement	Remark
	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 ; (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	

S.N.	Details of the requirement	Remark
	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: