Ref. No.: F.02(188)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2025/ 250 Dated:- 8/4/2025

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 (30.06.2027)

!! सर्वे सन्तु निरामयाः!!

LAST DATE OF SUBMISSION OF ONLINE BIDS	30.04.2025 at 6.00 PM
DATE AND TIME OF OPENING OF ONLINE TECHNICAL BIDS	01.05.2025 at 11.00 AM

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

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(188)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2025/250 Dated:- 8/4/2025

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(188)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2025/ Dated:-	120.00 Lakhs	MSC252650 B00002	30.04.2025 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

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

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 30.06.2027)

Bid Reference	:	**Ref. No.: F.02(188)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2025/** Dated:-
Date and time for downloading bid document	:	09.04.2025 from 6.00 PM
Pre- bid conference	:	17.04.2025 at 11.00 A.M. (RMSC Board Room)
Last date and time of submission of online bids	:	30.04.2025 up to 6.00 PM
Date and time of opening of Online technical bids	:	01.05.2025 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. 2360/- (including GST @ 18%)**
Empanelment Fee	:	**Rs. 5900/- (including GST @ 18%)**
Estimated Cost	:	**Rs. 120.00 Lakh**

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Reason: Approved

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 30.06.2027)

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 30.04.2025 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 30.06.2027**) 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. 25,000/-**
- **Processing fee of Rs. 2360/- (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 30.04.2025 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 30.04.2025 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. 25,000/- the Bids will be

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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. **Eligibility Criteria for Empanelment :-**

(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 **(2020-21, 2021-22, 2022-23)** or **(2021-22, 2022-23, 2023-24)** The same should be supported by audited annual accounts

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& 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

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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 the BANK OF MAHARASHTRA 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. **2020-21, 2021-22, 2022-23** or **2021-22, 2022-23, 2023-24** (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. **2020-21, 2021-22, 2022-23** or **2021-22, 2022-23, 2023-24 (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

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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 <u>and</u> 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**

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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. 25,000/- 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 30.04.2025 or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSCL on or before 30.04.2025 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**

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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 30.06.2027. 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 enclosed at Annexure-IX.

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 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

   for past
   for past
   for past

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

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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

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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.

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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.

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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.

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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.

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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. COMPLIANCE WITH THE CODE OF INTEGRITY AND NO CONFLICT OF INTEREST:

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.

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

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

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

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

Annexure - 1

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

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	2020-21	
2	2021-22	
3	2022-23	
Total		**Rs.** **Crore**
Average Annual Turnover		**Rs.** **Crore**

OR

S.No.	Years	Turnover in Crore (INR.)
1	2021-22	
2	2022-23	
3	2023-24	
Total		**Rs.** **Crore**
Average Annual Turnover		**Rs.** **Crore**

Date:

Seal:

UDIN NO.

Signature of Auditor/
Chartered Accountant

(Name in Capital)

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

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 :

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 [illegible]:41:10 IST
Reason: Approved

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 :

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

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:

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

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:

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

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:

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 13:41:10 IST
Reason: Approved

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.

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

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(188)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2025/** Dated:-

For the empanelment of analytical testing laboratories for the test and analysis of SURGICAL & SUTURES/MEDICAL DEVICES (Ending on **30.06.2027**) 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.	
4.	
5.	

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

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 [illegible]:41:10 IST
Reason: Approved

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

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 [illegible]:41:10 IST
Reason: Approved

Signature valid

Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 15:41:10 IST
Reason: Approved

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 :

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

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

SUTURES LIST

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Class As per Medical Device Rules 2017
1.	R-1	Absorbable Surgical Suture (Sterile Catgut),BP/USP Needled Suture Chromic (3/8 Cir RB Needle 40mm Length 76 cm)	1/0	12 Foils	Class C
2.	R-2	Absorbable Surgical Suture (Sterile Catgut),BP/USP Needled Suture Chromic (l/2 Cir RB Needle 20mm Length 76 cm)	3/0	12 Foils	Class C
3.	R-3	Absorbable Surgical Suture (Sterile Catgut),BP/USP Needled Suture Chromic (l/2 Cir RB Needle 30mm Length 76 cm)	2/0	12 Foils	Class C
4.	R-4	Absorbable Surgical Suture (Sterile Catgut), BP/USP Needled Suture Chromic (l/2 Cir RB Needle 30mm Length 76 cm)	1/0	12 Foils	Class C
5.	R-5	Absorbable Surgical Suture (Sterile Catgut), BP/USP Needled Suture Chromic (l/2 Cir RB Needle 40mm Length 76 cm)	1/0	12 Foils	Class C
6.	R-6	Absorbable Surgical Suture (Sterile Catgut), BP/USP Needled Suture Chromic (3/8 RB Needle 30mm Length 76 cm)	2/0	12 Foils	Class C
7.	R-7	Absorbable Surgical Suture (Sterile Catgut),BP/USP Needled Suture Chromic (1/2 Cir RB Needle 45 mm Length 100 cm)	1	12 Foils	Class C
8.	R-8	Absorbable Surgical Suture (Sterile Catgut), Needled Suture Chromic (3/8 Cir RCutting Needle 26mm, Length 76 cm)	3/0	12 Foils	Class C
9.	R-9	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) ½ Cir RB Needle 20mm length 70 cm	3/0	12 Foils	Class C
10.	R-10	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) 1/2 Cir RB Needle 30mm length 90 cm	2/0	12 Foils	Class C
11.	R-11	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) 1/2 Cir RB Needle 30mm **length75- 90 cm**	1/0	12 Foils	Class C
12.	R-12	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) 1/2 Cir Tapercut Needle (Heavy) **35-40mm** length **75-90 cm**	1	12 Foils	Class C
13.	R-13	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) ½ Cir RB Needle40mm length 90 cm	1	12 Foils	Class C

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
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Reason: Approved

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Class As per Medical Device Rules 2017
14.	R-14	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) (1/2 Cir Conventional 25mm length 90 cm)Undyed	3/0	12 Foils	Class C
15.	R-15	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) (1/2 Cir RB Needle 20mm length 70 cm)	4/0	12 Foils	Class C
16.	R-16	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) (1/2 Cir RB needle 40mm Length 90 cm	2/0	12 Foils	Class C
17.	R-17	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) (1/2 Cir RB Needle 40mm length 90 cm)	1/0	12 Foils	Class C
18.	R-18	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) 3/8 Circle Cutting Needle 22mm length 45 cm	3/0	12 Foils	Class C
19.	R-19	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide) 3/8 Circle Cutting 16mm Needle, Suture Length 70cm	4/0	12 Foils	Class C
20.	R-20	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK (1/2 Cir RB Needle 20mm, Length 76 cm)	3/0	12 Foils	Class C
21.	R-21	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK (3/8Cir Reverse Cutting Needle 26mm, Length 76 cm)	3/0	12 Foils	Class C
22.	R-22	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BLACK BRAIDED Silk (3/8Cir Reverse Cutting Needle 45mm, Length 76 cm)	2/0	12 Foils	Class C
23.	R-23	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYAMIDE MONOFILAMENT BLACK (NYLON) (3/8 Cir Micropoint Round Body ,6mm Length 38 cm)	8/0	12 Foils	Class C
24.	R-24	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYAMIDE MONOFILAMENT BLACK (NYLON) (3/8 Conventional Cutting Needle 16mm Length 70 cm)	3/0	12 Foils	Class C
25.	R-25	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYAMIDE MONOFILAMENT BLACK (NYLON) (3/8 Conventional Cutting Needle 19mm Length 60 cm.)	4/0	12 Foils	Class C
26.	R-26	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYAMIDE MONOFILAMENT BLACK (NYLON)	5/0	12 Foils	Class C

Signature valid

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Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Class As per Medical Device Rules 2017
		(3/8 Cir slim blade Cutting Needle 15mm Length 70 cm)			
27.	R-27	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYAMIDE MONOFILAMENT BLACK (NYLON) (3/8 Cir R Cutting Needle **40-45mm Length 60-70 cm.)**	2/0	12 Foils	Class C
28.	R-28	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYAMIDE MONOFILAMENT BLACK (NYLON) (3/8 Cir R Cutting Needle 45mm Length 70 cm.)	1/0	12 Foils	Class C
29.	R-29	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir RB 13 mm Needle,Length 75cm) Double Arm	5/0	12 Foils	Class C
30.	R-30	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (3/8Cir RB 16mm needle,Length 90 cm)	6/0	12 Foils	Class C
31.	R-31	NON ABSORBABLE SURGICAL SUTURE,STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (3/8Cir RB Double 8mm Needle, Length 60 cm)	7/0	12 Foils	Class C
32.	R-32	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (3/8Cir RB 16 mm Needle, Length 70 cm)	5/0	12 Foils	Class C
33.	R-33	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir RB Needle 30mm Length 90 cm)	1/0	12 Foils	Class C
34.	R-34	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir RB Heavy Needle **40-45mm Length 75-90 cm)**	1	12 Foils	Class C
35.	R-35	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir tapercut double needle cutting size **16-17mm Length 70-90 cm)**	5/0	12 Foils	Class C
36.	R-36	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir Tapercut Double Needle 17mm Length 70-90 cm)	4/0	12 Foils	Class C
37.	R-37	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir RB Needle 25mm, Length 90 cm) Double Arm	3/0	12 Foils	Class C
38.	R-38	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir RB Needle 30mm, Length 90 cm)	2/0	12 Foils	Class C

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Class As per Medical Device Rules 2017
39.	R-39	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir Tapercut Needle 17mm Length 75 cm) Double Arm	3/0	12 Foils	Class C
40.	R-40	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir Tapercut needle,25 mm Length 90 cm) Double Arm	2/0	12 Foils	Class C
41.	R-41	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE USP(3/8 Cir Conventional Cutting PC-3Needle 15mm Length 60cm)	6/0	12 Foils	Class C
42.	R-42	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (3/8 Cir RB 13mm Needle, Length 90 cm Double Arm	6/0	12 Foils	Class C
43.	R-43	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir RB needle 16 mm Length 70 cm)	4/0	12 Foils	Class C
44.	R-44	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (3/8 Cir Cutting Needle 25mm length 45 cm)	3/0	12 Foils	Class C
45.	R-45	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir RB Heavy 40mm, length 90 cm)	1	12 Foils	Class C
46.	R-46	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (l/2 Cir Reverse Cutting, 45 mm Needle length 100 cm)	1	12 Foils	Class C
47.	R-47	NON ABSORBABLE SURGICAL SUTURE, ,STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (3/8 Cir RB , 8mm Double Needle, Suture Length of 70Cm)	8/0	12 Foils	Class C
48.	R-48	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Circle Tapercut 13mm Double Needle 70cm)	4/0	12 Foils	Class C
49.	R-49	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Circle CC 13mm Needle, Suture Length of 70cm) DOUBLE ARM	5/0	12 Foils	Class C
50.	R-50	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Circle Tapercut Needle 17mm Suture Length of 90cm) Double Arm	2/0	12 Foils	Class C

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51.	R-51	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir RB Needle 25mm, Suture Length of 75cm) Double Arm	3/0	12 Foils	Class C
52.	R-52	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BRAIDED COATED POLYSTER,GREEN/WHITE or BLUE/WHITE Polybutylate / Silicon Coated Polyster Braided green/ blue (1/2 Cir Tapercut ,17 mm Double Needle, length 75 cm)	4/0	12 Foils	Class C
53.	R-53	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BRAIDED COATED POLYSTER,GREEN/WHITE or BLUE/WHITE Polybutylate / Silicon Coated Polyster Braided White (1/2 Cir Tapercut ,17 mm Double Needle, length 90 cm)	2/0	12 Foils	Class C
54.	R-54	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BRAIDED COATED POLYSTER,GREEN/WHITE or BLUE/WHITE Polybutylate / Silicon Coated Polyster Braided Green / Blue (1/2 Cir Tapercut ,17 mm Double Needle, length 90 cm)	2/0	12 Foils	Class C
55.	R-55	Non absorbable surgical suture sterilized surgical needled suture Polybutylate / Silicon Coated with Polyster Braided (Green / Blue) 1/2 Circle Taper cut , 17mm Double armed Needle, Suture Length of 90cm with pledgets Size 6 X 3 X 1.5mm	2/0	6 Foils	Class C
56.	R-56	Non absorbable surgical suture sterilized surgical needled suture Polybutylate / Silicon Coated with Polyster Braided (Green / Blue) *with 1/2 Circle Taper cut , 25mm Double armed Needle, Suture Length of 90cm with pledgets Size 6 X 3 X 1.5mm	2/0	6 Foils	Class C
57.	R-57	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BRAIDED COATED POLYSTER,GREEN/WHITE or BLUE/WHITE Coated Polyster Braided (Green / Blue) with 1/2 Circle Tapercut Double Needle 25mm, Suture Length 90 cm	3/0	12 Foils	Class C
58.	R-61	ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYGLECAPRONE / Polyglyconate, MONOFILAMENT SUTURES (1/2 Circle Oval RB Needle 26mm Needle, Suture Length of 70cm)	Size 2/0	12 Foils	Class C
59.	R-62	ABSORBABLE SURGICAL SUTURES POLYGLECAPRONE / Polyglyconate, MONOFILAMENT SUTURES (1/2 Circle Oval RB Contrast Needle 26mm, suture length 70cm)	3/0	12 Foils	Class C
60.	R-63	ABSORBABLE SURGICAL SUTURES Monofilament sutures Polyglecaprone /Polyglyconate (1/2 Circle Cutting 16mm Needle,suture length 70cm)	4/0	12 Foils	Class C
61.	R-64	ABSORBABLE SURGICAL SUTURES	3/0	12 Foils	Class C

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		POLYGLECAPRONE / Polyglyconate, MONOFILAMENT SUTURES (3/8 Circle Cutting24- 26mm Needle, Suture Length of **70-90cm**)			
62.	R-65	Absorbable Surgical Suture (Synthetic) Sterilised Needled Suture Monofilament Polydioxanone Violet (1/2 Circle Reverse Cutting 40-**50 mm Length 70- 90cm**)	1	12 Foils	Class C
63.	R-66	ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYDIOXANONE Violet (1/2 Circle RB 31mm Needle, Length 70cm)	2/0	36 Foils	Class C
64.	R-67	ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYDIOXANONE Violet (1/2 Circle RB 30mm Needle, Length 70cm)	1/0	12 Foils	Class C
65.	R-68	Absorbable Surgical Suture (Synthetic) antibacterial coated sterilised needled suture (Braided coated Polyglactin/ Polyglycolic Acid violet) 1/2 Circle CT round bodied 40mm, GS needle, suture length 90 cm/	1	12 Foils	Class C
66.	R-69	Absorbable Surgical Suture (Synthetic) antibacterial coated sterilised needled suture (Braided coated Polyglactin/ Polyglycolic Acid violet)1/2 circle CT round bodied 40mm, GS needle, suture length 90 cm	1/0	12 Foils	Class C
67.	R-70	Absorbable Surgical Suture (Synthetic) antibacterial coated sterilised needled suture (Braided coated Polyglactin / Polyglycolic Acid violet)1/2 circle round bodied 30mm, suture length 90 cm/	2/0	12 Foils	Class C
68.	R-71	Absorbable Surgical Suture (Synthetic) antibacterial coated sterilised needled suture (Braided coated Polyglactin/ Polyglycolic Acid violet)1/2 circle Reverse Cutting,OS 40mm, suture length 90 cm	1	12 Foils	Class C
69.	R-72	Absorbable Surgical Suture (Synthetic) antibacterial coated sterilised needled suture (Braided coated Polyglactin / Polyglycolic Acid violet)1/2 circle Reverse Cutting 36mm, OS needle, suture length 90 cm/	1/0	12 Foils	Class C
70.	R-73	Absorbable Surgical Suture (Synthetic) antibacterial coated sterilised needled suture (Braided coated Polyglactin / Polyglycolic Acid violet) 1/2 circle round bodied 20mm, suture length 70 cm	3/0	12 Foils	Class C
71.	R-74	Absorbable Surgical Suture (Synthetic) antibacterial coated sterilised needled suture (Braided coated Polyglactin/ Polyglycolic Acid violet)3/8 circle R Cutting, PS-1,24mm, suture length 70 cm	3/0	12 Foils	Class C
72.	R-75	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYAMIDE MONOFILAMENT BLACK (NYLON) (3/8 Cutting spatulated Edge Needle, Double arm Needle 6 mm, Suture length 30-42 cm	10/0	12 Foils	Class C
73.	R-76	Absorbable Surgical Suture (Sterile Catgut), Needled Suture Chromic (3/8 Cir RCutting Needle 16mm, Length	5/0	12 Foils	Class C

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		76 cm)			
74.	R-77	Absorbable Surgical Suture (Sterile Catgut), Needled Suture Chromic (3/8 Cir Cutting Needle 8mm, Length 35 cm)	6/0	12 Foils	Class C
75.	R-78	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK WITH NEEDLE Silk (3/8 Cir RB Needle 20mm, Length 76 cm)	4/0	12 Foils	Class C
76.	R-79	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK WITH NEEDLE Silk (3/8 Cir RB Needle 16mm, Length 76 cm)	5/0	12 Foils	Class C
77.	R-80	Absorbable Surgical Suture (Sterile Catgut), Needled Suture Chromic (3/8 Cir RCutting Needle 19mm Length 76 cm)	4/0	12 Foils	Class C
78.	R-81	Absorbable Surgical Suture, Sterilised Surgical Needled Suture Polyglyconate, Monofilament Sutures (1/2 Circle Oval RB Needle 26-30mm Needle, Suture Length of 70cm)	Size 2/0	12 foils	Class C
79.	R-82	Absorbable Surgical Suture Polyglyconate, Monofilament Sutures (l/2 Circle Oval RB Contrast Needle 20-26mm, suture length 70cm)	Size 3/0	12 foils	Class C

*** For item code R-68 to R-74 bidders should quote the rates including Antibacterial test.**

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SURGICAL LIST

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
1.	S-1	Absorbable Gelatin Sponge IP 66, Size 80(+-10) mm x 50 mm x 10 mm should be sterlized.	Piece	Class C
2.	S-3	Asepto Syringe with Transparent Bulb Sterile, 60 ml	Piece	ND
3.	S-4	Blood Administration Set / Blood Transfusion Set • Sharp and easy piercing spike suitable for blood bags and standard blood containers • Transparent cylindrical drip chamber with filter. Filter size should be 200+20 micrometer. • 150 cm long smooth kink resistant tubing • Efficient roller clamp to control and adjust the transfusion rate • As per IS 9824(Part 3):1996	Unit	Class B
4.	S-5(a)	Disposable Sterile Surgical Rubber Gloves Size 6 ½ Inches • Made of natural rubber Latex, powdered, without tear, properly folded in a paper • Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less • Tensile strength as per EN 455-2 • Powder should be non-allergenic • As per IS 13422 • ISI marked / CE certified / FDA approved	Pair	ND
5.	S-5(b)	Disposable Sterile Surgical Rubber Gloves Size 6 ½ Inches • Made of natural rubber Latex, **powder free (Polymer /Silicon Coated),** without tear, properly folded in a paper • Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less • Tensile strength as per EN 455-2 • As per **IS 13422** ISI marked / CE certified / FDA approved **(CE Certification / FDA Approval for item is mandatory for importer firms, that cannot avail IS Standards)**	Pair	ND
6.	S-6(a)	Disposable Sterile Surgical Rubber Gloves Size 7 Inches • Made of natural rubber Latex, powdered, without tear, properly folded in a paper • Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less • Tensile strength as per EN 455-2 • Powder should be non-allergenic • As per IS 13422 • ISI marked / CE certified / FDA approved	Pair	ND
7.	S-6(b)	Disposable Sterile Surgical Rubber Gloves Size 7 Inches • Made of natural rubber Latex, **powder free (Polymer /Silicon Coated),** without tear, properly folded in a paper • Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less • Tensile strength as per EN 455-2 • As per **IS 13422** ISI marked / CE certified / FDA approved **(CE Certification / FDA Approval for item is mandatory for importer firms, that cannot avail IS Standards)**	Pair	ND
8.	S-7(a)	Disposable Sterile Surgical Rubber Gloves Size 7½ Inches • Made of natural rubber Latex, powdered, without tear, properly folded in a paper	Pair	ND

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less • Tensile strength as per EN 455-2 • Powder should be non-allergenic • As per IS 13422 • ISI marked / CE certified / FDA approved		
9.	S-7(b)	Disposable Sterile Surgical Rubber Gloves Size 7 ½ Inches • Made of natural rubber Latex, **powder free (Polymer /Silicon Coated),** without tear, properly folded in a paper • Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less • Tensile strength as per EN 455-2 • As per **IS 13422** ISI marked / CE certified / FDA approved **(CE Certification / FDA Approval for item is mandatory for importer firms, that cannot avail IS Standards**	Pair	ND
10.	S-8(a)	Suction Catheter, Sterile. Size: FG 5 (For use in respiratory tract) • Soft, kink resistant tubing • Rounded open tip with lateral eye • Colour coded universal funnel connector for safe connection to standard suction equipment • Length 50 cm (min.) • As per IS0 8836:2014	Each Piece	Class B
	S-8(b)	Suction Catheter, Sterile. Size: FG 6 (For use in respiratory tract) • Soft, kink resistant tubing • Rounded open tip with lateral eye • Colour coded universal funnel connector for safe connection to standard suction equipment • Length 50 cm (min.) • As per IS0 8836:2014	Each piece	Class B
11.	S-8(c)	Suction Catheter, Sterile. Size: FG 8 (For use in respiratory tract) • Soft, kink resistant tubing • Rounded open tip with lateral eye • Colour coded universal funnel connector for safe connection to standard suction equipment • Length 50 cm (min.) • As per IS0 8836:2014	Each piece	Class B
12.	S-8(d)	Suction Catheter, Sterile. Size: FG 10 (For use in respiratory tract) • Soft, kink resistant tubing • Rounded open tip with lateral eye • Colour coded universal funnel connector for safe connection to standard suction equipment • Length 50 cm (min.) • As per IS0 8836:2014	Each piece	Class B
13.	S-8(e)	Suction Catheter, Sterile. Size: FG 12 (For use in respiratory tract) • Soft, kink resistant tubing • Rounded open tip with lateral eye • Colour coded universal funnel connector for safe connection to standard suction equipment • Length 50 cm (min.) • As per IS0 8836:2014	Each piece	Class B

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
14.	S-8(f)	Suction Catheter, Sterile. Size: FG 14 (For use in respiratory tract) • Soft, kink resistant tubing • Rounded open tip with lateral eye • Colour coded universal funnel connector for safe connection to standard suction equipment • Length 50 cm (min.) • As per IS0 8836:2014	Each piece	Class B
15.	S-8(g)	Suction Catheter, Sterile. Size: FG 16 (For use in respiratory tract) • Soft, kink resistant tubing • Rounded open tip with lateral eye • Colour coded universal funnel connector for safe connection to standard suction equipment • Length 50 cm (min.) • As per IS0 8836:2014	Each piece	Class B
16.	S-8(h)	Suction Catheter, Sterile. Size: FG 18 (For use in respiratory tract) • Soft, kink resistant tubing • Rounded open tip with lateral eye • Colour coded universal funnel connector for safe connection to standard suction equipment • Length 50 cm (min.) • As per IS0 8836:2014	Each piece	Class B
17.	S-8(i)	Suction Catheter, Sterile. Size: FG 20 (For use in respiratory tract) • Soft, kink resistant tubing • Rounded open tip with lateral eye • Colour coded universal funnel connector for safe connection to standard suction equipment • Length 50 cm (min.) • As per IS0 8836:2014	Each Piece	Class B
18.	S-8(j)	Suction Catheter, Sterile. Size: FG 22 (For use in respiratory tract) • Soft, kink resistant tubing • Rounded open tip with lateral eye • Colour coded universal funnel connector for safe connection to standard suction equipment • Length 50 cm (min.) • As per IS0 8836:2014	Each Piece	Class B
19.	S-9(a)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size 8 FG • Made of Silicone elastomer bonded with Latex • Should have hard plastic valve • Smooth distal end with smooth eyes for atraumatic intubation • Symmetrical foley balloon • Balloon capacity 3- 5 ml • As per IS 11497 • Color coding marking to identify size • Length, wall thickness and balloon capacity should be mentioned as per IS 11497. • Specification for B,C,D,E,F,G should be mentioned as per IS 11497 for particular size	Each Piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
20.	S-9(b)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size10 FG • Made of Silicone elastomer bonded with Latex • Should have hard plastic valve • Smooth distal end with smooth eyes for atraumatic intubation • Symmetrical foley balloon • Balloon capacity 3- 5 ml • As per IS 11497 • Color coding marking to identify size • Length, wall thickness and balloon capacity should be mentioned as per IS 11497. • Specification for B,C,D,E,F,G should be mentioned as per IS11497 for particular size	Each Piece	Class B
21.	S-9(c)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size16 FG • Made of Silicone elastomer bonded with Latex • Should have hard plastic valve • Smooth distal end with smooth eyes for atraumatic intubation • Symmetrical foley balloon • Balloon capacity 30 ± 1 ml • As per IS 11497 • Color coding marking to identify size • Length, wall thickness and balloon capacity should be mentioned as per IS 11497. • Specification for B,C,D,E,F,G should be mentioned as per IS11497 for particular size	Each Piece	Class B
22.	S-9(d)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size18 FG • Made of Silicone elastomer bonded with Latex • Should have hard plastic valve • Smooth distal end with smooth eyes for atraumatic intubation • Symmetrical foley balloon • Balloon capacity 30 ± 1 ml • As per IS 11497 • Color coding marking to identify size • Length, wall thickness and balloon capacity should be mentioned as per IS 11497. • Specification for B,C,D,E,F,G should be mentioned as per IS11497 for particular size	Each Piece	Class B
23.	S-9(e)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size20 FG • Made of Silicone elastomer bonded with Latex • Should have hard plastic valve • Smooth distal end with smooth eyes for atraumatic intubation • Symmetrical foley balloon • Balloon capacity 30 ± 1 ml • As per IS 11497 • Color coding marking to identify size	Each piece	Class B

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• Length, wall thickness and balloon capacity should be mentioned as per IS 11497. • Specification for B,C,D,E,F,G should be mentioned as per IS11497 for particular size		
24.	S-9(f)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size22 FG • Made of Silicone elastomer bonded with Latex • Should have hard plastic valve • Smooth distal end with smooth eyes for atraumatic intubation • Symmetrical foley balloon • Balloon capacity 30 ± 1 ml • As per IS 11497 • Color coding marking to identify size • Length, wall thickness and balloon capacity should be mentioned as per IS 11497. • Specification for B,C,D,E,F,G should be mentioned as per IS11497 for particular size	Each piece	Class B
25.	S-9(g)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size 24 FG • Made of Silicone elastomer bonded with Latex • Should have hard plastic valve • Smooth distal end with smooth eyes for atraumatic intubation • Symmetrical foley balloon • Balloon capacity 30 ± 1 ml • As per IS 11497 • Color coding marking to identify size • Length, wall thickness and balloon capacity should be mentioned as per IS 11497. • Specification for B,C,D,E,F,G should be mentioned as per IS11497 for particular size	Each piece	Class B
26.	S-10 (a)	Infant Feeding Tube Size:10FG length 50 cm (min.) • Two lateral eyes at distal end • Soft, kink resistant non-toxic PVC tubing, non irritant to delicate mucosa • With female flexible mount with in-built closure • Radio opaque line • Sterile	Each Piece	Class B
27.	S-10 (b)	Infant Feeding Tube Size:8FG, length 50 cm (min.) • Two lateral eyes at distal end • Soft, kink resistant non-toxic PVC tubing, non irritant to delicate mucosa • With female flexible mount with in-built closure • Radio opaque line • Sterile	Each Piece	Class B
28.	S-10 (c)	Infant Feeding Tube Size:5FG length 50 cm (min.) • Two lateral eyes at distal end • Soft, kink resistant non-toxic PVC tubing, non irritant to delicate mucosa • With female flexible mount with in-built closure • Radio opaque line • Sterile	Each Piece	Class B

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
29.	S-11	Sterile Disposable Perfusion Set with Airway and Needle (Adult Use) • For gravity feed only • Sharp and easy piercing spike with air vent • Transparent and flexible drip chamber • 150 cm long smooth kink resistant tubing • Self sealing latex bulb which will also act as an port for extra medication • Efficient roller clamp to control and adjust the fluid rate • 21 G needle • As per IS 12655 -4 standard	Unit	Class B
30.	S-12	Sterile Disposable Perfusion Set (Infusion set) with Airway and Needle (Paediatric Use) • Burette type measured volume chamber of 100 ml • Drop size of approx 60 drops per ml • Injection port,latexfree, for intermittent medication. • Floating auto shut off valve **(latex free)** in burette. • Soft and kink resistant PVC tubing. • Roller controller for flow control • Tube length 150 cm • 23G needle • **As per ISO 8536-5**	Unit	Class B
31.	S-13	Sterile Disposable Infusion Set with Microdrip (I.V.) • Microdrip Infusion set with drop size reduced to approx 60 drops per ml • Sharp and easy piercing spike • Transparent and flexible drip chamber • 150 cm long smooth kink resistant tubing • Efficient roller clamp to control and adjust the fluid rate • As per IS 12655 - 4 standard	Unit	Class B
32.	S-14	Insulin syringe (40 units) with (fixed) 30 G needle As per (phle Shall conform to tha)IS 12227	Unit	Class B
33.	S-15 (a)	Sterile Disposable (Single Use) Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock. Size 16G • Should be packed in transparent, single blister pack. • As per IS 10555 standard	Each Piece	Class B
34.	S-15 (b)	Sterile Disposable (Single Use Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock.) Size 18G • Should be packed in transparent, single blister pack. • As per IS 10555 standard	Each Piece	Class B
35.	S-15 (c)	Sterile Disposable (Single Use) Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock. Size 20G • Should be packed in transparent, single blister pack. • As per IS 10555 standard	Each Piece	Class B
36.	S-15 (d)	Sterile Disposable (Single Use) Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock. Size 22G • Should be packed in transparent, single blister pack. • As per IS 10555 standard	Each Piece	Class B
37.	S-15 (e)	Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula without port. Size 24G • Suitable for paediatric & neonatal use	Each Piece	Class B

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• Should be packed in transparent, single blister pack. • As per IS 10555 standard		
38.	S-16	Mucus Extractor Sterile • Clear transparent container • Antibacterial filter • Soft, kink resistant PVC tubing • Tube Size 10 FG; Length 40 cm (min.) • Capacity 25 ml	Unit	Class B
39.	S-17(a)	Nasal Oxygen Cannula (Set), Twin Bore (accessory for compressed air breathing) All Sizes (Adult) • Soft and kink resistant PVC tubing • Multichannel / star lumen to preventing accidental kinking • Twin bores should ensure equal volume of oxygen to both air passages • Connector for easy connection to the oxygen source • Tube length 200 cm	Each Piece	Class B
40.	S-17(b)	Nasal Oxygen Cannula (Set), Twin Bore (accessory for compressed air breathing) All Sizes (Pediatrics) • Soft and kink resistant PVC tubing • Multichannel / star lumen to preventing accidental kinking • Twin bores should ensure equal volume of oxygen to both air passages • Connector for easy connection to the oxygen source • Tube length 200 cm	Each Piece	Class B
41.	S-18	Adhesive Surgical Paper Tape (with cutter) Size 1" X 9.0 mts • Breathable, Hypo-allergenic, Latex Free, Non-woven and micro-porous backing material. • High quality water soluble adhesive for gentle bonding, holds well on damp skin and clean removal with minimal residue. • Should conform to the Standard and test prescribed in applicable IS (14944) and BP Standard.	Unit	Class B
42.	S-19	Adhesive Surgical Paper Tape (with cutter) Size 2" X 9.0 mts • Breathable, Hypo-allergenic, Latex Free, Non-woven and micro- porous backing material. • High quality water soluble adhesive for gentle bonding, holds well on damp skin and clean removal with minimal residue. • Should conform to the Standard and test prescribed in applicable IS (14944) and BP Standard.	Unit	Class B
43.	S-20	Adhesive Surgical Paper Tape (with cutter) Size 3" X 9.0 mts • Breathable, Hypo-allergenic, Latex Free, Non-woven and micro- porous backing material. • High quality water soluble adhesive for gentle bonding, holds well on damp skin and clean removal with minimal residue. • Should conform to the Standard and test prescribed in applicable IS (14944) and BP Standard.	Unit	Class B
44.	S-21	Plaster of Paris Bandages 15cm X 2.7mts / Roll Testing Parameter Should Be Followed As Per BP Standard	Unit	Class B
45.	S-22	Plaster of Paris Bandages 10cm X 2.7mts / Roll Testing Parameter Should Be Followed As Per BP Standard	Unit	Class B

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
46.	S-23 (a)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 10 • Soft, kink resistant PVC tubing for atraumatic intubation • Closed distal end should be coned with radio opaque material for accurate intubation • Four lateral eyes for greater efficiency • Radio opaque line • Marking at 50, 60, 70 cm from tip • Colour coded funnel • With luer connector / closure • Length 105 cm	Each Piece	Class B
47.	S-23 (b)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 12 • Soft, kink resistant PVC tubing for atraumatic intubation • Closed distal end should be coned with radio opaque material for accurate intubation • Four lateral eyes for greater efficiency • Radio opaque line • Marking at 50, 60, 70 cm from tip • Colour coded funnel • With luer connector / closure • Length 105 cm	Each Piece	Class B
48.	S-24 (a)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 14 • Soft, kink resistant PVC tubing for atraumatic intubation • Closed distal end should be coned with radio opaque material for accurate intubation • Four lateral eyes for greater efficiency • Radio opaque line • Marking at 50, 60, 70 cm from tip • Colour coded funnel • With luer connector / closure • Length 105 cm	Each Piece	Class B
49.	S-24 (b)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 16 • Soft, kink resistant PVC tubing for atraumatic intubation • Closed distal end should be coned with radio opaque material for accurate intubation • Four lateral eyes for greater efficiency • Radio opaque line • Marking at 50, 60, 70 cm from tip • Colour coded funnel • With luer connector / closure • Length 105 cm	Each Piece	Class B
50.	S-24 (c)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 18 • Soft, kink resistant PVC tubing for atraumatic intubation • Closed distal end should be coned with radio opaque material for accurate intubation • Four lateral eyes for greater efficiency • Radio opaque line • Marking at 50, 60, 70 cm from tip • Colour coded funnel	Each Piece	Class B

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Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• With luer connector / closure • Length 105 cm		
51.	S-25(a)	Scalp Vein Set (Disposable): Size 18G • Butterfly shaped wings for easy handling and attachment with skin. Colour coded • Needle should be bevelled, siliconised and should ensure atraumatic cannulation • Female luer fitting at one end • Soft, kink resistant, non-toxic, non irritant tube • Sterile	Each Piece	Class B
52.	S-25(b)	Scalp Vein Set (Disposable): Size 20G • Butterfly shaped wings for easy handling and attachment with skin. Colour coded • Needle should be bevelled, siliconised and should ensure atraumatic cannulation • Female luer fitting at one end • Soft, kink resistant, non-toxic, non irritant tube • Sterile	Each Piece	Class B
53.	S-25(c)	Scalp Vein Set (Disposable): Size 22G • Butterfly shaped wings for easy handling and attachment with skin. Colour coded • Needle should be bevelled, siliconised and should ensure atraumatic cannulation • Female luer fitting at one end • Soft, kink resistant, non-toxic, non irritant tube • Sterile	Each Piece	Class B
54.	S-25(d)	Scalp Vein Set (Disposable): Size 24G • Butterfly shaped wings for easy handling and attachment with skin. Colour coded • Needle should be bevelled, siliconised and should ensure atraumatic cannulation • Female luer fitting at one end • Soft, kink resistant, non-toxic, non irritant tube • Sterile	Each Piece	Class B
55.	S-26	Sterile Hypodermic Syringe with Needle attached, 24G, Single Use - 2 ml • Clear transparent chamber • Prominent graduation • Inert material gasket at the piston to minimise friction during movement & prevent leakage and back flow • Sharp needle ensuring minimum trauma during penetration • As per IS 12050 • Packing: Needle should be attached with the syringe and packed in unit ribbon pack • The words **"DESTROY AFTER SINGLE USE"** or **equivalent** should be written on Unit Container.	Unit	Class B
56.	S-27	Sterile Hypodermic Syringe with Needle attached, 24G, Single Use - 5 ml • Clear transparent chamber • Prominent graduation	Unit	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• Inert material gasket at the piston to minimise friction during movement & prevent leakage and back flow • Sharp needle ensuring minimum trauma during penetration • As per IS 12050 • Packing: Needle should be attached with the syringe and packed in unit ribbon pack • The words **"DESTROY AFTER SINGLE USE"** or **equivalent** should be written on Unit Container.		
57.	S-28	Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 10 ml • Clear transparent chamber • Prominent graduation • Inert material gasket at the piston to minimise friction during movement & prevent leakage and back flow • Sharp needle ensuring minimum trauma during penetration • As per IS 12050 • Packing: Needle should be attached with the syringe and packed in unit ribbon pack • The words **"DESTROY AFTER SINGLE USE"** or **equivalent** should be written on Unit Container.	Unit	Class B
58.	S-29	Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 20 ml • Clear transparent chamber • Prominent graduation • Inert material gasket at the piston to minimise friction during movement & prevent leakage and back flow • Sharp needle ensuring minimum trauma during penetration • As per IS 12050 • Packing: Needle should be attached with the syringe and packed in unit ribbon pack • The words **"DESTROY AFTER SINGLE USE"** or **equivalent** should be written on Unit Container.	Unit	Class B
59.	S-30 (a)	Surgical Blade Sterile, Size 11 • Single peel pack in metal foil • The tip of the blade shall be well defined, central and sharp. There shall be no waviness, jags, feathers, nicks, or other defects on the cutting edge. The surfaces of the blade shall be smooth and free from tool marks and any sign of corrosion. • As per IS 3319	100Blades/ Packet	ND
60.	S-30 (b)	Surgical Blade Sterile, Size 15 • Single peel pack in metal foil • The tip of the blade shall be well defined, central and sharp. There shall be no waviness, jags, feathers, nicks, or other defects on the cutting edge. The surfaces of the blade shall be smooth and free from tool marks and any sign of corrosion. • As per IS 3319	100Blades/ Packet	ND
61.	S-30 (c)	Surgical Blade Sterile, Size 22 • Single peel pack in metal foil • The tip of the blade shall be well defined, central and sharp. There shall be no waviness, jags, feathers, nicks, or other defects on the cutting edge. The surfaces of the blade shall be smooth and free from tool marks and any sign	100Blades/ Packet	ND

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		of corrosion. • As per IS 3319		
62.	S-39(a)	Sterile Disposable Spinal Needle for Single Use 22G x 3 ½ inch • Clear / transparent hub • Sharp tip which should ensure minimal puncture trauma	Each piece	Class B
63.	S-39(b)	Sterile Disposable Spinal Needle for Single Use 25G x 3 ½ inch • Clear / transparent hub • Sharp tip which should ensure minimal puncture trauma	Each piece	Class B
64.	S-40	Urine Collecting Bag, Disposable 2000 ml • Transparent sheet • Kink resistant flexible tubing not less than 90 cm in length • should have non-return valve • Top drainage outlet • Graduated bag • Moulded handle for easy handling	Unit	ND
65.	S-41 (a)	Double J Stent, Sterile, Both Ends Open - size 4F, length 16 cm • Radio opaque • Should be of inert material, non- irritant to tissue	Each piece	Class B
66.	S-41 (b)	Double J Stent, Sterile, Both Ends Open, size 5F, length 20 cm • Radio opaque • Should be of inert material, non- irritant to tissue	Each piece	Class B
67.	S-42 (a)	Double J Stent, Sterile, One End Closed - size 4F, length 16 cm • Radio opaque • Should be of inert material, non- irritant to tissue	Each piece	Class B
68.	S-42 (b)	Double J Stent, Sterile, One End Closed, size 5F, length 20 cm • Radio opaque • Should be of inert material, non- irritant to tissue	Each piece	Class B
69.	S-43(a)	Endotracheal Tube, Plain - Size 2.5mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
70.	S-43(b)	Endotracheal Tube, Plain - Size 3mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
71.	S-43(c)	Endotracheal Tube, Plain - Size 3.5mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
72.	S-43(d)	Endotracheal Tube, Plain - Size 4mm • Transparent • Standard 15 mm connector at proximal end	Each piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile		
73.	S-43(e)	Endotracheal Tube, Plain - Size 4.5mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
74.	S-43(f)	Endotracheal Tube, Plain - Size 5mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
75.	S-43(g)	Endotracheal Tube, Plain - Size 5.5mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
76.	S-43 (h)	Endotracheal Tube, Plain with radio-opaque line, Sterile, Single Use - Size 6mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
77.	S-43(i)	Endotracheal Tube, Plain - Size 6.5mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
78.	S-43(j)	Endotracheal Tube, Plain - Size 7mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
79.	S-43(k)	Endotracheal Tube, Plain - Size 7.5mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
80.	S-43(l)	Endotracheal Tube, Plain - Size 8mm • Transparent	Each piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile		
81.	S-43(m)	Endotracheal Tube, Plain - Size 8.5mm • Transparent • Standard 15 mm connector at proximal end • Radio-opaque line throughout the length • Tip suitable for nasal and oral intubation • Single use, sterile	Each piece	Class B
82.	S-44(a)	Endotracheal Tube, Cuffed - Size 4mm • Soft cuff towards the distal end • Kink resistant inflation tube • Murphy eye at distal end with polished smoothness • Radio-opaque line • Standard 15 mm connector • Sterile, single use • Curved shaped blister pack – suiting the shape of product	Each piece	Class B
83.	S-44(b)	Endotracheal Tube, Cuff - Size 4.5mm • Soft cuff towards the distal end • Kink resistant inflation tube • Murphy eye at distal end with polished smoothness • Radio-opaque line • Standard 15 mm connector • Sterile, single use • Curved shaped blister pack – suiting the shape of product	Each piece	Class B
84.	S-44 (c)	Endotracheal Tube, Cuff - Size 5mm • Soft cuff towards the distal end • Kink resistant inflation tube • Murphy eye at distal end with polished smoothness • Radio-opaque line • Standard 15 mm connector • Sterile, single use • Curved shaped blister pack – suiting the shape of product	Each Piece	Class B
85.	S-44 (d)	Endotracheal Tube, Cuff - Size 6mm • Soft cuff towards the distal end • Kink resistant inflation tube • Murphy eye at distal end with polished smoothness • Radio-opaque line • Standard 15 mm connector • Sterile, single use • Curved shaped blister pack – suiting the shape of product	Each Piece	Class B
86.	S-44 (e)	Endotracheal Tube, Cuff - Size 6.5mm • Soft cuff towards the distal end • Kink resistant inflation tube • Murphy eye at distal end with polished smoothness • Radio-opaque line • Standard 15 mm connector	Each Piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• Sterile, single use • Curved shaped blister pack – suiting the shape of product		
87.	S-44(f)	Endotracheal Tube, Cuff - Size 7mm • Soft cuff towards the distal end • Kink resistant inflation tube • Murphy eye at distal end with polished smoothness • Radio-opaque line • Standard 15 mm connector • Sterile, single use • Curved shaped blister pack – suiting the shape of product	Each piece	Class B
88.	S-44(g)	Endotracheal Tube, Cuff - Size 7.5 • Soft cuff towards the distal end • Kink resistant inflation tube • Murphy eye at distal end with polished smoothness • Radio-opaque line • Standard 15 mm connector • Sterile, single use • Curved shaped blister pack – suiting the shape of product	Each piece	Class B
89.	S-44(h)	Endotracheal Tube, Cuff - Size 8 • Soft cuff towards the distal end • Kink resistant inflation tube • Murphy eye at distal end with polished smoothness • Radio-opaque line • Standard 15 mm connector • Sterile, single use • Curved shaped blister pack – suiting the shape of product	Each piece	Class B
90.	S-44(i)	Endotracheal Tube, Cuff - Size 8.5 • Soft cuff towards the distal end • Kink resistant inflation tube • Murphy eye at distal end with polished smoothness • Radio-opaque line • Standard 15 mm connector • Sterile, single use • Curved shaped blister pack – suiting the shape of product	Each piece	Class B
91.	S-44(j)	Endotracheal Tube, Cuff - Size 9 • Soft cuff towards the distal end • Kink resistant inflation tube • Murphy eye at distal end with polished smoothness • Radio-opaque line • Standard 15 mm connector • Sterile, single use • Curved shaped blister pack – suiting the shape of product	Each piece	Class B
92.	S-45	Tracheostomy Tube (PVC), Plain, Sterile, Single Use - All Sizes • Soft flexible flange at for easy fixation • 15 mm connector at terminal end which can be rotated in 360 degree direction • Non-irritant • Radio-opaque line	Each Piece	Class B

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
93.	S-46	Tracheostomy Tube (PVC), Cuffed, Sterile, Single Use - All Sizes • Soft flexible flange at for easy fixation • 15 mm connector at terminal end which can be rotated in 360 degree direction • Non-irritant • Radio-opaque line • Balloon with non return valve	Each Piece	Class B
94.	S-47(a)	Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag (2000 ml) (size 24) • Graduated Bag • Should have well fitting cap • Soft drainage catheter 50 cm long, with radio opaque line • Rounded open distal end with smooth atraumatic eyes in catheter • Catheter with markings at 2 cm interval	Each Piece	Class B
95.	S-47(b)	Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag (2000 ml) (size 28) • Graduated Bag • Should have well fitting cap • Soft drainage catheter 50 cm long, with radio opaque line • Rounded open distal end with smooth atraumatic eyes in catheter • Catheter with markings at 2 cm interval	Each Piece	Class B
96.	S-47(c)	Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag (2000 ml) (size 32) • Graduated Bag • Should have well fitting cap • Soft drainage catheter 50 cm long, with radio opaque line • Rounded open distal end with smooth atraumatic eyes in catheter • Catheter with markings at 2 cm interval	Each Piece	Class B
97.	S-73	Polypropylene Nonabsorbable Synthetic Surgical Mesh 7.5 cmX 15 cm soft to feel fast edges,slightly stretchbonding.	Piece	Class C
98.	S-74	Polypropylene Nonabsorbable Synthetic Surgical Mesh 15 cmX 15 cm soft to feel fast edges,slightly stretchbonding.	Piece	Class C
99.	S-79	Sterilized Umbilical Cotton Tape Width 3 mm, Length 75 cm Should conform to Schedule F(III) of Drug and Cosmetic Act 1940	Each piece	Class A
100.	S-80	Bone Wax Sterilised	2.5 gm/ Packet	Class C
101.	S-82	Skin Graft Knife Blade (Sterile) (disposable) Skin Grafting Knife Blade (Sterile) made of carbon steel or stainless steel material 158 mm long individually wrapped in wrapper corrosion inhibitor paper in single packet,. In packs of 10. The edge must be sharp enough to cut the skin in a single shave and should snugly fit in the handle As per IS IS 3759.	One Pack EACH	ND
102.	S-84(a)	K Wire, length 375 mm; 1mm Length of wire should be mentioned with specification. As per IS 8261	Each Unit	Class B
103.	S-84(b)	K Wire, length 375 mm;1.6mm • Length of wire should be mentioned with specification. • As per IS 8261	Each Unit	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
104.	S-84(c)	K Wire, length 375 mm; size 1.8mm • Length of wire should be mentioned with specification. As per IS 8261	Each Unit	Class B
105.	S-85	• Face Mask, Disposable • Should be manufactured from non woven poly prop fabric • Should be 3 ply construction • Should have high bacterial filtration efficiency • Should be heat sealed to keep 3 layers together • Standard size 17.5 x9 cm • Color green/blue • There should be a string each at all four corners,length of string should be 40cm • Nose clip should be there • No elastic band.	Piece	ND
106.	S-86 (a)	Surgical Cap, Disposable (For Surgeons) • Should be manufactured from non woven fabric. • **Strip for tying** the cap stitched on the back for proper grip on the forhead. • Green colour • Ultrasonically stitched • Air permeable/breathable • Should retain skin and hair particle. • Strip for tying the cap	Piece	ND
107.	S-86 (b)	Surgical Cap, Disposable (For Nurses) • Should be manufactured from non woven fabric • Blue / Green colour • Round upon wearing, with elastic • Air permeable / breathable • Should retain skin and hair particles	Piece	ND
108.	S-87(a)	Foldable Intra Ocular lense with injector (Size + 11 D to +17.5 D) Size:6mm optics. 12-13mm total diameter 1. Made of foldable Acrylic (Hydrophobic) material 2. Bi-Convex single piece IOL with aspheric optics 3. Size:6mm optics. 12-13mm total diameter. 4. Modified C loop haptic/plate haptics (5. IOL should have UV blocking capability 6. IOL should have 360°square edge.. 7. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision 8. Diopters- + 11 D to +17.5 D at 0.5 D step. 9. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified.	Each piece	Class C
109.	S-87(b)	Foldable Intra Ocular lense with injector (Size + 18 D to + 24 D) Size:6mm optics. 12-13mm total diameter	Each piece	Class C

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		1. Made of foldable Acrylic (Hydrophobic) material 2. Bi-Convex single piece IOL with aspheric optics 3. Size:6mm optics. 12-13mm total diameter. 4. Modified C loop haptic/plate haptics 5. IOL should have UV blocking capability 6. IOL should have 360°square edge.. 7. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision 8. Diopters- + 18 D to + 24 D at 0.5 D step. 9. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified.		
110.	S-87(c)	Foldable Intra Ocular lense with injector (Size + 24.5 D to + 28.5 D) Size:6mm optics. 12-13mm total diameter 1. Made of foldable Acrylic (Hydrophobic) material 2. Bi-Convex single piece IOL with aspheric optics 3. Size:6mm optics. 12-13mm total diameter. 4. Modified C loop haptic/plate haptics 5. IOL should have UV blocking capability 6. IOL should have 360°square edge.. 7. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision 8. Diopters- + 24.5 D to + 28.5 D at 0.5 D step. 9. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified.	Each piece	Class C
111.	S-88(a)	Standard PMMA Intra Ocular Lenses (Size + 11 D to +17.5 D) • 6mm optic size 12.5 - 13.0 mm total diameter, Biconvex 1. PMMA optics and haptics single piece with hole 2. 6mm optic size 12.5 to 13mm total diameter, Biconvex 3. IOL haptics – modified C shaped with 5° -10° anterior angulation. 4. Should have 360° square edges. 5. IOL should have UV blocking capability 6. Diopters- + 11 D to +17.5 D at 0.5 D step. 7. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified.	Each piece)	Class C
112.	S-88(b)	Standard PMMA Intra Ocular Lenses (Size + 18 D to + 24 D) • 6mm optic size 12.5 - 13.0 mm total diameter, Biconvex 1. PMMA optics and haptics single piece with hole 2. 6mm optic size 12.5 to 13mm total diameter, Biconvex 3. IOL haptics – modified C shaped with 5° -10° anterior angulation.	Each piece	Class C

Signature valid
Digitally signed by Manoj Kumar
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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		4. Should have 360° square edges. 5. IOL should have UV blocking capability 6. Diopters- + 18 D to + 24 D at 0.5 D step. 7. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified.		
113.	S-88(c)	Standard PMMA Intra Ocular Lenses (Size + 24.5 D to + 28.5 D) 6mm optic size 12.5 - 13.0 mm total diameter, Biconvex 1. PMMA optics and haptics single piece with hole 2. 6mm optic size 12.5 to 13mm total diameter, Bioconvex 3. IOL haptics – modified C shaped with 5° -10° anterior angulation. 4. Should have 360° square edges. 5. IOL should have UV blocking capability 6. Diopters- + 24.5 D to + 28.5 D at 0.5 D step. 7. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified.certified.	Each piece	Class C
114.	S-89(a)	Disposable Sterile Surgical Rubber Gloves Size 8 Inches • made of natural rubber latex- powdered,without tear,properly folded in a paper • As per IS **13422** • ISI marked/CE certified/FDA approved • Colour code marking to designate size	Pair	ND
115.	S-89(b)	Disposable Sterile Surgical Rubber Gloves Size 8 Inches • made of natural rubber latex- powder free,without tear,properly folded in a paper • As per IS **13422** • ISI marked/CE certified/FDA approved • Colour code marking to designate size	Pair	ND
116.	S-90(a)	Rubber examination gloves made of natural rubber latex. Non-sterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Extra Small. **Should bear BIS certificate of IS 15354** **CE marked/ISO 13485 (for importer)**	Dispenser Box of 100 Gloves	ND
117.	S-90 (b)	Rubber examination gloves made of natural rubber latex. Non-sterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Small **Should bear BIS certificate of IS 15354** **CE marked/ ISO 13485 (for importer)**	Dispenser Box of 100 Gloves	ND
118.	S-90 (c)	Rubber examination gloves made of natural rubber latex. Non-sterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Medium **Should bear BIS certificate of IS 15354** **CE marked /ISO 13485 (for importer)**	Dispenser Box of 100 Gloves	ND
119.	S-90 (d)	Rubber examination gloves made of natural rubber latex. Non-sterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting	Dispenser Box of 100	ND

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		powder USP. Large **Should bear BIS certificate of IS 15354** **CE marked/ ISO 13485 (for importer)**	Gloves	
120.	S-91	Pressure Monitoring Line / High Pressure Extension Line • Suitable for high pressure monitoring and for connection between syringe infusion pump and patient • Male luer lock at one end and female luer lock at other end ; should fit all standard equipment. Luer lock connectors should provide secure fitting. • Pressure upto 800 psi • Length 200 cm • Sterile	Each piece in Blister Pack	Class B
121.	S-92	Urine Collecting Bag for new born / Paediatric urine collecting Bag • Should have suitability for both male and female patients • Should be provided with adhesive for fixation and good grip with minimal risk of allergy and injury • Capacity 100 ml • Sterile	Each piece	ND
122.	S-93	Umbilical Catheter (for New Born) All sizes • Radio opaque line • With female flexible mount • Colour coded connector • Open tip should be soft, rounded, atraumatic • Length 40 cm	Each Piece	Class B
123.	S-94	Umbilical Cord Clamp • Suitable for clamping umbilical cord of new born • Security lock to prevent accidental opening after clamping • Grooved clamping area	Each piece	Class A
124.	S-95	Absorbable Oxidized Regenerated Cellulose net size 2"x 3" Topical Absorbable Haemostatic Bactericidal Property	Each piece	Class D
125.	S-96A	Close wound Drainage Device under negative pressure (Closed Wound Suction Unit) • Option to use one or two catheters simultaneously • Bellow chamber with capacity 800 ml • Bellow unit with connector • Graduated Bellow • Connecting tube with clamp and "Y"connector • Curved needle / trocar with catheter • Multiperforated catheter / Radon drain with radio opaque line • Catheter 16 FG	Each Piece(	Class B
126.	S-96B	Close wound Drainage Device under negative pressure (Closed Wound Suction Unit) • Option to use one or two catheters simultaneously • Bellow chamber with capacity 800 ml • Bellow unit with connector • Graduated Bellow • Connecting tube with clamp and "Y"connector • Curved needle / trocar with catheter	Each Piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• Multiperforated catheter / Radon drain with radio opaque line • Catheter 18 FG		
127.	S-98	Bone cement with antibiotics,fast and slow setting	40 GM PACK	Class C
128.	S-99	Sanitary Napkins (for Menstrual Hygiene) Specifications:- • Sanitary Napkin consists of an outer covering provided with sufficient number of channels for leak protection and an absorbent filler material. • The Sanitary Napkins shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling. Should be odourless. • The material used in fabrication shall be non allergenic. • Shall be free from acids and alkali. • Each primary package shall contain 6 napkins in a polyethylene bag of good quality which As per IS size of product and sealed properly. • Both upper and lower sheets shall be white in colour. • As per IS 5405. • Type of material and size should be mentioned as per IS 5405 • Instruction for usage should be mentioned on every packet.		
129	S-99(a)	Sanitary Napkin, Beltless 1. Covering – Covering of the absorbent filler shall be good quality knitted sleeve or **non-woven fabric** which has sufficient porosity to permit the assembled napkin to meet the absorbency requirements. The napkins shall have a non absorbent barrier on one side which shall have an identifying mark indicating the side of the barrier. 2. Absorbent Filler – The filler material shall consist of cellulose pulp/ wadding, and shall be free from lumps, oil spots, dirt or foreign material, etc. 3. Back Strip – A back strip for sticking the sanitary napkin onto the underwear should be there using good quality adhesive material. 4. Size - The size of absorbent section / complete sanitary napkin shall be as follows: (in mm) Absorbent section Total Pad Length 210 +_ 10 230 +_ 10 Width 60 to 75 70 to 85 Thickness 8 +_ 2 5. Weight : **Not more than** 10 gm . . Instruction for usage should be mentioned on every packet **Instruction for usage should be mentioned on every packet** **(B). Disposable Individual Pouch/Wrapper for Each Sanitary Napkin (as per notification of Ministry of Environment, Forest and Climate Change Dated 08.04.2016)** **Pouch/Wrapper Specifications:-** **1- Pouch/wrapper should be of the size of Sanitary Napkin being supplied.** **2- It should have adhesive to seal the sanitary napkin within.** **3- Pouch/Wrapper should not be transparent.** **Note:- Instruction for use of disposable pouch/wrapper must be written in Hindi on disposable pouch/wrapper -** **"इस्तेमाल किये हुये सेनेटरी नेपकिन को मोड कर Disposable Pouch/Wrapper में**	6 napkins per pack	ND

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		डाले एवं **Pouch/Wrapper** को गोंद लगी पट्टी से बन्द कर सुरक्षित तरीके से कूडेदान में डालें। "		
129.	S-99(b)	Sanitary Napkin, Belttype 1. Covering – Covering of the absorbent filler shall be good quality knitted sleeve or **non-woven fabric** which has sufficient porosity to permit the assembled napkin to meet the absorbency requirements. The napkins shall have a non absorbent barrier on one side which shall have an identifying mark indicating the side of the barrier. 2. Absorbent Filler – The filler material shall consist of cellulose pulp/ wadding, and shall be free from lumps, oil spots, dirt or foreign material, etc 3. Size - The size of absorbent section / complete sanitary napkin shall be as follows: (in mm) Absorbent section Absorbing Pad Length **220 +_ 10(overall pad length 550+-10mm) with absorbing pad lying in the center** Width 70 +_ 5 Thickness **17 +_ 3** 4. Weight : **12 +_ 3 gm** 5. Pack – Six napkins in a pack. 6. Elastic Belt with loops shall be provided in each pack. 7. Absorbency: The napkin should be able to absorb not less than 30 ml of normal saline or coloured water or test fluid when poured on to the centre of the napkin at the rate of 15 ml per minute. .Instruction for usage should be mentioned on every packet.	6 napkins per pack	ND
130.	S-99(P)	**Name of Item-** Belt-less Sanitary Napkin with wings 1. Covering (Absorbing top sheet character)–Good Quality knitted sleeve or non woven fabric of rash free, non irritant and soft to touch material which has sufficient porosity to permit the assembled napkin to meet absorbency requirements. The napkins shall have a non absorbent barrier on one side with adhesive covered by a differently identifiable paper 2.Overall Length (mm) 230 ± 5 3.Core length 220 mm± 10 4.Fluff core/pad length 220 mm± 10 5. Over all width with wings 160mm+_5 6.Fluff core/pad length 70 mm± 5 7.Thickness of a single pad 9-10mm 8. Weight of a single pad : 8-10 gm 9. Pack Six napkins in a pack. 10 Type.- Belt-less Sanitary Napkin with wings 11. Minimum Absorbency: 50ml 12.pH value of absorbent material 6-8.5 B. DISPOSABLE Individual **pouch** for each sanitary napkin(as per notification of ministry of environment, forest and climate change dated 08.04.2016) Pouch specifications:- 1. Pouch should be of the size of sanitary napkin being supplied. 2. It should have adhesive to seal the sanitary napkin within. 3. Pouch should not be transparent.	6napkins per pack	ND

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		Note:-Instructions for use of disposable pouch must be written in Hindi on disposable pouch. इस्तेताल किये हुये सेनेटरी नेपकिन को मोड कर Disposable Pouch में डाले एवं Disposable Pouch को गोंद लगी पट्टी से बन्द कर सुरक्षित तरीके से कूडेदान में डालें।		
131.	S-100	Oxygen mask (Adult) • Mould Facemask with adjustable elastic strap for proper position of mask on the mouth and nasal area • Friendly soft medical PVC material fitting better and more comfortable. • Aluminium nasal clip provides better fixation. • Anatomical design provides lighter seal. • Latex free elastic strap available.	UNIT	ND
132.	S-101	Oxygen mask (Paediatric) • Mould Facemask with adjustable elastic strap for proper position of mask on the mouth and nasal area • Friendly soft medical PVC material fitting better and more comfortable. • Aluminium nasal clip provides better fixation. • Anatomical design provides lighter seal. • Latex free elastic strap available. • Mask connector 4M	UNIT	ND
133.	S-102	Sterile Catheter, single Use, for Urinary Drainage(Foley Balloon Catheter), 2 way, Size 14 • Made of Silicone elastomer bonded with Latex • Should have hard plastic valve • Smooth distal end with smooth eyes for a traumatic intubation • Symmetrical Foley Balloon • Balloon Capacity 30+-1 ml • As per IS 11497 • Color coding marking to identify size • Length, wall thickness and ballon capacity should be mentioned as per IS 11497 • Specification for B,C,D,E,F,G should be mentioned as per IS 11497	Each piece	Class B
134.	S-103	• Nelaton-catherer size14FG Distal end is close and proximal end has female colour code connector • Soft, Kink resistant medical grade PVC tube • Length:40 cm • Individually packed in poly and sterile	Each PIECE	Class B
135.	S-104	ECG Electrode •Reliable trace, •High conductivity,• Easy to handle	Each Piece	Non drug
136.	S-105	Surgical Blade Sterile, Size 23 • Single peel pack in metal foil • The tip of the blade shall be well defined, central and sharp. There shall be no waviness, jags, feathers, nicks, or other defects on the cutting edge. The surfaces of the blade shall be smooth and free from tool marks and any sign of corrosion.	Each Piece	Non drug

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• As per IS 3319(Mandatory)		
137.	S-106	Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 50 ml • Clear transparent chamber • Prominent graduation • Inert material gasket at the piston to minimise friction during movement & prevent leakage and back flow • Sharp needle ensuring minimum trauma during penetration • As per (phle Shall conform to tha)IS 12050 • Packing: Needle should be attached with the syringe and packed in unit ribbon pack • The words "DESTROY AFTER SINGLE USE" or equivalent should be written on Unit Container.	Each Piece	Class B
138.	S-107	Urethral Catheter 90 (FG-14), made up of medical grade PVC	Each Piece	Class B
139.	S-108	Urethral Catheter 91 (FG-10), made up of medical grade PVC	Each Piece	Class B
140.	S-109	Vaccum Suction Set, 2.5 meter Length, •Suction handle with Suction Tube •Sterile,• Pyrogenic Free, •Latex free,• Single use	Each Piece	Class B
141.	S-110	Epidural Minipack 18G, **80mm – 90mm**, Metal Stylet For Single Use only, •Sterile, •Epidural catheter 20G, L·90 cm, • **3 to 6 Lateral Holes** closed end, •Borst Adapter •Epidural Catheter Flat filter 0.2 micro meter •Thread Assist Guide •LOR (Loss of resistance) **plastic syringe 6ml/10ml**	Each Piece	Class B
142.	S-111	Vascular Catheter 16G/5FR, double lumen length 40cm.USFDA/ four digit notified CE approved, should have two guide wire 45cm & 80cm or more (Logline IV.) Peel-Away Sheath Glide Thru 5fr*10 cm, Guide wire Nitinol 80 cm, Guide wire Nitinol 45 cm Introducer Needle 21 G *7 CM, Syringe - 10 ml tuer-lock, Skin Protectant Prep Pad, second site Adjustable Hub, Measuring Tape, 5 fr pressure Injectable PICC Line with blue flex tip 40 cm, Dressing STATLOOCK stabilization Device (Suture less)	Each Piece	Class B
143.	S-112	Vascular Catheter with metal Guide wire, 4Fr Single Lumen, distalvalve, saline flush only Size 45cm or more USFDA/ four digit notified CE approved (Logline IV.) Internal stylet, Statlock Stabilization device (Suture less), Introducer Needle, Micro introducer with Vessel Dilator, Guide wire- 50 Cm Nitinol, Safety Scalpel,Suture Wing, End Cap	Each Piece	Class B
144.	S-113	Vascular Catheter with metal Guide wire 3Fr single lumen,micro introducer,contrast Media compatible, Size 45cm or more (Logline IV.) USFDA/ four digit notified CE approved Syringe 12 ml,Internal stylet,Measuring Tape,Stat lock catheter Stabilization device (Suture less), Introducer safety peripheral IV catheter 20G, Micro introducer with Vessel Dilator,Guide wire-50 Cm Nitinol,Needle introducer 21 G, Safety Scalpel,	Each Piece	Class B

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		End Cap		
145.	S-114	Vascular Catheter 7FR-16 CM with chlorhexidine, silver sulfadiazine coated triple lumen USFDA/four digit notified CE approved. Introducer Needle 18 G., spring guide wire 45 cm J tip, Dilator 8.5 Fr., Raulerson spring Introduction syringe 5 ml	Each Piece	Class B
146.	S-115	Vascular Catheter 5Fr/16G, double lumen length 50cm.USFDA/four digit notified CE approved. should have two guide wire 45 cm & 80cm or more(Logline IV.) Peel-Away Sheath Glide Thru 5fr *10 cm, Guide wire Nitinol 80 cm, Guide wire Nitinol 45 cm, Introducer Needle 21 G *7 CM, Syringe-10 ml luer-lock, Skin Protectant Prep Pad, second site Adjustable Hub, Measuring Tape,5 fr pressure Injectable PICC Line with blue flex tip 50 cm, Dressing STATLOOCK stabilization Device (Suture less)	Each Piece	Class B
147.	S-116	Vascular Catheter 5fr/16G, double lumen length 55cm.USFDA/ four digit notified CE approved, should have two Guide wire 45cm & 80cm or more (Logline IV.) Peel-Away Sheath Glide Thru 5fr *10 cm,Guide wire Nitinol 80 cm,Guide wire Nitinol 45 cm,Introducer Needle 21 G*7 CM, Syringe-10 ml luer-lock, Skin Protectant Prep Pad, second site Adjustable Hub, Measuring Tape,5 fr pressure Injectable PICC Line with blue flex tip 55cm, Dressing STATLOOCK stabilization Device (Suture less)	Each Piece	Class B
148.	S-117	Vascular Catheter with metal Guide wire 5Fr Double lumen, Introducer safety PIV Catheter20G, 45cm or more (Logline IV.) USFDA/ four digit notified CE approved Syringe 12 ml, Internal stylet, Measuring Tape, Stat lock catheter Stabilization device (Suture less), Introducer safety peripheral IV catheter 20G,Micro introducer with Vessel Dilator,Guide wire-50 Cm Nitinol,Needle Introducer 21 G,Safety Scalpel, End Cap	Each Piece	Class B
149.	S-118	Vascular Catheter with Metal Guide wire,5Fr Triple Lumen, Size range 55cm or more (Logline IV:) USFDA/four digit notified CE approved Syringe 12 ml, Internal stylet, Measuring Tape, Stat lock catheter Stabilization device (Suture less), Introducer safety peripheral IV catheter 20G,Micro Introducer with Vessel Dilator, Guide wire-50 Cm Nitinol, Needle Introducer 21 G, Safety Scalpel,End Cap	Each Piece	Class B
150.	S-119	3 Way Stop Cock , Non Pyrogenic & Single Use, should be leak proof, with smooth movements	Each Piece	Class B
151.	S-120	3 Way Stop Cock with extension Tube (**Vein-O Extension line**) size 10 cm (Non Pyrogenic & Single Use)	Each Piece	Class B
152.	S-121	3 Way Stop Cock with extension Tube (**Vein-O Extension line**) size 50 cm (Non Pyrogenic & Single Use)	Each Piece	Class B
153.	S-122	3 Way Stop Cock with extension Tube (**Vein-O Extension line**) size 100 cm (Non Pyrogenic & Single Use)	Each Piece	Class B
154.	S-123	3 Way Stop Cock with extension Tube (**Vein-O Extension line** size 150 cm (Non Pyrogenic & Single Use)	Each Piece	Class B
155.	S-124	Abdominal Drain Kit, Sterile, having drainage catheter and Collection Bag (2000 ml) (size 16)	Each Piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		• Graduated Bag, • Should have well fitting cap • Soft drainage catheter 50 cm long, with radio opaque line • Rounded open distal end with smooth atraumatic eyes in catheter • Catheter with markings at 2 cm interval		
156.	S-125	Abdominal Drain Kit, Sterile, having drainage catheter and Collection Bag (2000 ml) (size 20) • Graduated Bag • Should have well fitting cap • Soft drainage catheter 50 cm long, with radio opaque line • Rounded open distal end with smooth atraumatic eyes in catheter • Catheter with markings at 2 cm interval	Each Piece	Class B
157.	S-126	Nasal Pronge Neonatal (Flexible Medical Grade, 2 Meter Long, Multichannel Kink Resistance Tube	Each Piece	Class B
158.	S-127	**Elastic Adhesive Bandage BP 10 cm x 1 mtr Stretched Length** Adhesive material should have good quality sticking property, non-allergic	Each Piece	Class B
159.	S-128	Sterile Disposable (Single Use Teflon/PTFE I.V Cannula with integrated 3 way stop cock Size 26G · Should be packed in transparent single blister pack · Should confirm to IS 10555 standard · (Neonatal IV Cannula Size 26)	Each Piece	Class B
160.	S-129	NIV Mask (Noninvasive Ventilation Mask) Adult · Should be light weight silicon based full face & nasal mask with face & forehead soft cushion pads should have variable pressure inflatable cushion for adults in Large size. Should be with ergonomically designed clips/straps for easy disengagement of the head gear. Should be Single Use for Ventilator without vent. Non allergic, leak proof, contour should be maintained. USFDA/ CE four Digit notify body approved.	Each Piece	Non Drug
161.	S-130	NIV Mask (Noninvasive Ventilation Mask) Adult • Should be light weight silicon based full face & nasal mask with face &forehead soft cushion pads should have variable pressure inflatable cushion for adults in Large size. Should be with ergonomically designed clips/straps for easy disengagement of the head gear. Should be Single Use for BiPAP with vent.Non allergic, leak proof, contour should be maintained. USFDA/ CE four Digit notify body approved.	Each Piece	Non Drug
162.	S-131	NIV Mask (Noninvasive Ventilation Mask) Adult · Should be light weight silicon based full face & nasal mask with face &forehead soft cushion pads should have variable pressure inflatable cushion for adults in Large size.Should be with ergonomically designed clips/straps for easy disengagement of the head gear. Should be Single Use for BiPAP with vent.Non allergic, leak proof, contour should be maintained. USFDA/ CE four Digit notify body approved.	Each Piece	Non Drug
163.	S-132	NIV Mask (Noninvasive Ventilation Mask) Adult • Should be light weight silicon based full face & nasal mask with face &forehead soft cushion pads should have variable pressure inflatable cushion for adults in Medium size.Should be with ergonomically designed clips/straps for easy disengagement of the head gear. Should be Single Use for BiPAP with vent. Non allergic, leak proof, contour should be maintained. USFDA/ CE four Digit notify body approved.	Each Piece	Non Drug
164.	S-133	NIV Mask (Noninvasive Ventilation Mask) Paediatric • Should be light weight oro nasal mask with soft cushion pads in small size • Should be with ergonomically designed clips/straps for easy	Each Piece	Non Drug

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		disengagement of head gear • Should be Single Use with Bronchoscopy port CO2 &O2 port with chin support • Non allergic, leak proof, contour should be maintained		
165.	S-134	1. Compatibile with any standard Nebulizer/high/flow oxygen. 2. Made of transparent ,soft,clear,non-toxic, non-irritant , latex free material. 3. Storage Humidity Range = 90%RH 4. Soft, kink resistant minimum 2 meter long non- collapsible extension on tubing to be connected with Nebulizer/oxygen source. 5. Consist of Adult (Large) Mask with pull through elastic strip to hold in place . 6. Anatomically contoured for comfort /nose clip on mask preferable. 7. Should have leak/spillage proof nebulizer chamber. 8. The mask nebulizer chamber and tubing should be sterilizable . 9. Should with stand gas flow of at least 10ltr/min. 10.Particles sizes should be below 5 microns if used with oxygen or nebulizer 11. Nebulizes 3cc within 10 minutes.	Each Piece	Non Drug
166.	S-135	1. Compatibile with any standard Nebulizer/high/flow oxygen. 2. Made of transparent ,soft,clear,non-toxic, non-irritant , latex free material. 3. Storage Humidity Range = 90%RH 4. Soft, kink resistant minimum 2 meter long non- collapsible extension on tubing to be connected with Nebulizer/oxygen source. 5. Consist of Paediatric Mask with pull through elastic strip to hold in place. 6. Anatomically contoured for comfort /nose clip on mask preferable. 7. Should have leak/spillage proof nebulizer chamber. 8. The mask nebulizer chamber and tubing should be sterilizable . 9. Should with stand gas flow of at least 10ltr/min. 10.Particles sizes should be below 5 microns if used with oxygen or nebulizer 11. Nebulizes 3cc within 10 minutes.	Each Piece	Non Drug
167.	S-136	Chemotherapy Port &Non-coring needles(Adult) • Valved catheter need only saline flush, catheter with intermediate size port with small septum and silicon filled suture holes, should be MRI compatible with cathlock radio-opaque ring. 8FR with silicon material with peel apart percutaneous introducer system. • Chemo port huber needle 20g and 22g.	Each Piece	Class B
168.	S-137	Chemotherapy Port &Non-coring needles(Pediatric) • catheter need only saline flush, catheter with intermediate size power port with large septum and silicon filled suture holes, should be MRI compatible with cathlock radio-opaque ring. 6FR with silicon material with peel apart percutaneous introducer system • Chemo port huber needle 20g and 22g.	Each Piece	Class B
169.	S-	Core biopsy instrument with compatible co-axial needle	Each Piece	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
	138	(Automatic disposal) Should be bevel tip.Should have adjustable penetration depth of 18mm and 25 mm with automatic and semi-automatic firing modes in single instrument/gun. Should have fire ready indicator to reduce the risk of premature instrument firing.Should have advanced Echogenic Technology for enhanced visibility in ultrasound. Should be available with compatible coaxial needle in a single kit. Instrument / Gun Size: 18 Gauge, 16cm with Coaxial Needle Size: 17 Gauge, Total Cannula Length 12.9cm.		
170.	S-139	Disposable bone marrow biopsy needle Should have ergonomic two- piece T-handle design. Should have trocar tapered stylet point for easy coring of bone.Should have triple crown cannula tip with 6 cutting cannula facets.Should be available with marrow acquisition cradle with sample size verification marking. 11Gauge, 4 inch Length	Each Piece	
171.	S-140	Eyelid occlusion dressing Should have width of 3.5 to 4.0 cm & Length of 9.5 to 10.0cm, Dual Zonel with Central Zone as Transparent window, Material-100% polyurethane Clear Film layer, Made up of Polyester Non-Woven Fabric, Latex Free, Solvent based Acrylic adhesive, A set of 2 sterile dressing , CE Certified.	Each Piece	
172.	S-141	Eye pressure shield Should be made up of Soft Foam and Rigid Plastic Shield, Length of 178 to 185 mm and width of 83 to 88mm, Foam Thickness of 17 to 19mm. Plastic Type Triton TX-2001, Enough holes on Nasal rib and either side of the shield to prevent condensation, Weight not more than 50gms; CE Certified.	Each Piece	
173.	S-99 P 2	**Belt-less Sanitary Napkin with wings** 1. Covering (Absorbing top sheet charactor)–Good Quality knitted sleeve or non woven fabric of rash free, non irritant and soft to touch material which has sufficient porosity to permit the assembled napkin to meet absorbency requirements. The napkins shall have a non absorbent barrier on one side with adhesive covered by a differently identifiable paper 2.Overall Length (mm) 280 ± 5 3.Core length 265 mm± 5 4.Fluff core pad length 265 mm± 5 5. Overall width with wings (mm) 160mm+_5 **6.Thickness of a single pad (mm) 9-10mm** 7. Weight of a single pad : 8-10 gm 8. Pack Six napkins in a pack. 9 Type.- Belt-less Sanitary Napkin with wings 10. **Minimum Absorbency:** 50ml 11.pH value of absorbent material 6-8.5 12. DISPOSABLE Individual pouch for each sanitary napkin(as per norms ministry of environment; forest and climate change dated 08.04.2016)	6 napkins per pack	

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		Pouch specifications:- **1. Pouch should be of the size of sanitary napkin being supplied.** 2. It should have adhesive to seal the sanitary napkin within. **3. Pouch should not be transparent.** **4.It should have UDAAN logo on the sanitary napkin packet.** **5.Instruction for use of disposable pouch must be written in Hindi.** Note:-**Instructions for use of disposable pouch must be written in Hindi on disposable pouch .** इस्तेमाल किये हुये सेनेटरी नेपकिन को मोड कर **Disposable Pouch में डाले एवं Disposable Pouch को** गोंद लगी पट्टी से बन्द कर सुरक्षित तरीके से कूडेदान में डालें।		
174.	NES5	Qunituple Penta Blood Bag 450 ml CPDA	Each piece	
175.	NES6	Qunituple Penta Blood Bag 350 ml CPDA	Each piece	
176.	NES8	Single Blood Bags {350ml)	Each Piece	
177.	NES9	Double Blood Bags with SAGM (350ml)	Each Piece	
178.	NES10	Double Blood Bags with SAGM (450ml)	Each Piece	
179.	NES11	Triple Blood Bags with SAGM (350ml)	Each Piece	
180.	NES12	Triple Blood Bags with SAGM (450ml)	Each Piece	
181.	NES13	Quadruple Blood Bags with SAGM (350ml)	Each Piece	
182.	NES14	Quadruple Blood Bags with SAGM (450ml)	Each Piece	
183.	NE 32 A	**Specifications of Bed side Leucodepletion Filters for Blood Transfusion:-(For one unit of red cell)** **1. Filters should be able to leuco-deplete red cells form leukocyte contamination separately for 1 unit of red cells.** **2. Filters should be having the capacity of log 4 reduction (99.99%)** **3. Filters should not carry any charges it should be neutrally charged.** **4. Filters material should be polyester woven / non- woven.** **5. Leukocytes should be consistently averaging less than 0.5x105 residual leucocytes for one unit of red cell. RBC recovery should be averaging more than 90%.** **6. Filters should have hard / soft housing for optical monitoring.** **7. Filtration loss should not be more than 35 ml for one unit red cell.** **8. Should have integrated ≥ 40 µm, micro aggregate filter.** **9. Should be US FDA/ European CE Certified.** **10. Filter should have air vent, to achieve transfusion with minimum loss.** **11. Packing Unit – Filter should have individual packing with bulk box pack. Quantity should be in multiple of 05 units**	Filter should have individual packing with bulk box pack	
184.	NE 32 B	**Specifications of Bed side Leucodepletion Filters for Blood Transfusion:-(For two unit of red cell)**	Filter should have individual packing with bulk box pack	

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		1. Filters should be able to leuco-deplete red cells form leukocyte contamination separately for 1 unit of red cells and for 2 units of red cells each. 2. Filters should be having the capacity of log 4 reduction (99.99%) 3. Filters should not carry any charges it should be neutrally charged. 4. Filters material should be polyester woven / non- woven. 5. Leukocytes should be consistently averaging less than 0.5x105 residual leucocytes for one unit of red cell and 0.2*106 for two units of red cell. RBC recovery should be averaging more than 90%. 6. Filters should have hard / soft housing for optical monitoring. 7. Filtration loss should not be more than 35 ml for one unit red cell. 8. Should have integrated ≥ 40 µm, micro aggregate filter. 9. Should be US FDA/ European CE Certified.		
185.	NES-15	**HIV (ELISA) testing kits IV generation.** 1. Should be solid phase micro plate coated HIV I & II recombinant and/or synthetic peptide antigens and antibody to HIV 1 p24. 2. The assay should detect HIV 1 and II antibodies and HIV 1p24 antigen. 3. Micro wells coated with a mixture of recombinant HIV antigens gp120, gp41 and gp36 & monoclonal antibodies to HIV p24 antigen. 4. Analytical sensitivity of p24 Ag should not be less than 20 pg/ml. 5. Adequate documents detailing the principle, components, details of antigen for antibody, detection of HIV 1 and 2 Antigen, bio- safety, methodologies validity, criteria interpretation of results, performance characteristics, storage conditions, limitation of assays manufacturing, & expiry dates should be provided with each kit. 6. The kit should have approval of the statutory authority in its country of origin. 7. In case of imported kits it should be registered and licensed under the provisions of Drugs & cosmetics Act and rules/ or Medical devices rules 2017 in India. 8 In case of indigenous manufacturers should be licensed under the provisions of Drugs & cosmetics, Act and rules and or medical devices rules 2017 issued by the competent authority defined under Drugs and Cosmetics Act, 1940, 9. The kit should have minimum remaining shelf- life of 5/6" or 12 months {Whichever is more) the port of discharge of consignees, 10. The assay component should include reactive (for both antibody as well as antigen) and non- reactive controls with each kit. 11. The assay should have sensitivity level of 100% and specificity level of more than or equal to 99%. 12. The manufacturer should ensure maintenance of cold chain during storage & transport the kits at 2°c - 8°C. The temperature indicator should be placed on every pack of kit. 13. The pack size should be 96 tests/kit.	Each Piece	
186.	NES-17	**Hepatitis B Surface Antigen (Elisa) Testing Kits IV Generation/High sensitive** 1. An ELISA reader based qualitative test 2. Should have polyclonal antibodies coated on the solid. phase & monoclonal antibodies in the conjugate to detect all subtypes &	Each Piece	

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		mutant strains. The assay should be able to detect surface antigen to hepatitis B virus. 3. Total incubation time should not be more than 90 minutes. 4. Adequate documents detailing the principle components, bio- safety methodologies, validity criteria, interpretation of results, performance characteristics storage conditions, limitation of assays manufacturing & expiry dates should be provides with each kit. 5. The kit should have approval of the statutory authority in its country of origin. 6. In case of imported kits it should be registered and licensed under the provisions of Drugs & Cosmetics act and rules and/or medical devices rules 2017 in India, 7. In case of indigenous manufacturers should be licensed under the provisions of Drugs & cosmetics Act and rules and or medical devices rules 2017 issued by the competent authority defined under Drugs and cosmetics act, 1940. 8. The kit should have minimum shelf- life of 5/6th or 12 months (whichever is more) at the port of discharge of consignees. 9. The assay component should include reactive and non- reactive controls. 10. The assay should have sensitivity of 100% and specificity of more than or equal to 99% 11. The assay should have analytical sensitivity of detecting less than or equal to 50pg/ml. 12. All the reagents should in ready to use form. Only wash buffer concentrate to be reconstituted before use. The manufacturer should ensure maintenance of cold chain during storage & transport the kits at 2°c - 8°C. Temperature indicator to be placed on every box of kits. 13. The kit size should be 96 tests/kit.		
187.	NES-18	**HCV (Elisa) Testing Kits IV Generation** 1. Microplate ELISA coated with recombinant/ synthetic peptide antigens for core. NS3 NS4 and NSS and antibody to HCV core Antigen. 2. Should be based on Indirect Assay for Antibody detection & Sandwich for Antigen detection. 3. Total Incubation time should not be more than 150 minutes. 4. Positive & negative controls for antigen & antibody should be ready to use. 5. Adequate documents detailing the principle, components, bio- safety	Each Piece	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		methodologies validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays manufacturing & expiry dates should be provided with each kit. 6. The kit to be procured should have approval of the statutory authority in its country of origin. 7. In case of imported kits it should be registered and licensed under the provisions of Drugs cosmetics Act and rules and/or medical devices rules 2017 in India. 8. In case of indigenous manufacturers should be licensed under the provisions of Drugs &cosmetics Act and rules and or medical devices rules 2017 issued by the competent authority defined under Drugs and cosmetics act 1940. 9. The kit should have minimum shelf- life of 5/6thor 12 months (whichever is more) at the port of discharge of consignees. 10. The assay component should include reactive (for both antibody and antigen) and non- reactive controls. 11. The assay should have a sensitivity of 100% and specificity of more than or equal to 98%. 12. The manufacturer should ensure maintenance of cold chain during storage & transport the kits at 2°c - 8°c. The time temperature indicator should be placed on every pack of kits. 13. The pack size should be 96 tests/kit.		
188.	NES-19	**HIV (Rapid) testing kits** 1. Test should be a solid coated HIV 1 & HIV II recombinant and/or synthetic peptide antigens. 2. The assay/test assay should detect total antibodies (IgG, IgM & IgA) specific to HIV-1 & HIV-2 in human serum, plasma & whole blood. 3. The assay should utilize recombinant HIV-1 capture antigens i.e. gp41 and gp120) for detection of HIV 1 antibodies & recombinant HIV-2 capture antigen i.e. gp36 detection of HIV 2 antibodies. 4. Adequate documents detailing the principle, components, details of antigen for antibody detection of HIV 1 and 2, bio- safety methodologies validity criteria interpretation of results performance characteristics storage conditions limitation of assays manufacturing & expiry dates should be provided with each kit. 5. The kit should have approval of the statutory authority in its country of origin. 6. In case of imported kits it should be registered and licensed under the provisions of drugs & cosmetics act and rules and/ or medical devices rules 2017 in India. 7. In case of indigenous manufacturers should be licensed under the provisions of drugs & cosmetics act and rules and or medical devices Rules 2017 issued by the competent authority defined under drugs	Each Piece	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		and· cosmetics act, 1940. 8. The kit should have minimum shelf- life of 5/6thor 12 months (whichever is more) at the port of discharge of consignees. 9. The time required of performing the test should not be more than 20 minutes. 10. The control dot/ band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant for merely checking the flow of reagents or integrity of the antigen. Except for lateral flow assays 11. The assay should have sensitivity of 100% and specificity of 99 % or more with documentary evidence. 12. The test kit should be packed such that there is a provision to conduct single test at a time. 13. The pack size should not be more than 50 tests/kits. 14. The storage & transport temperature of the Kit should be 2-30°C.		
189.	NES-20	**Hepatitis B surface antigen (Rapid) testing kits** 1. Should be solid phase/ particle coated with monoclonal antibodies to HBsAg 2. The assay should be able to detect surface antigen to Hepatitis B virus. 3. The assay should be able to detect all 11 sub types of HBsAg. 4. The assay should utilize the combination of Monoclonal & polyclonal antibodies to HBsAg for detection. 5. Adequate documents detailing the principle components, bio- safety methodologies, validity criteria, interpretation of results, performance characteristics storage conditions, limitation of assays manufacturing & expiry dates should be provides with each kit. 6. The kit should have approval of the statutory authority in its country of origin. 7. In case of imported kits it should be registered and licensed under the provisions of Drugs & Cosmetics act and rules and/or medical devices rules 2017 in India. 8. In case of indigenous manufacturers should be licensed under the provisions of Drugs & cosmetics Act and rules and. or medical devices rules 2017 issued by the competent authority defined under Drugs and cosmetics act, 1940, 9. The kit should have minimum shelf- life of 5/6th or 12 months (whichever is more) at the port of discharge of consignees. 10. The total procedure time shall not be more than 30 minutes. 11. Assay should have Sensitivity 100% & specificity 100% or more with documentary evidence. 12. The storage & transport temperature of the Kit should be 2-30°C. 13. The pack size should not be more than 50 tests wherein each test is individually packed.	Each Piece	
190.	NES-21	**HCV (Ragid) testing kits**	Each Piece	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		1. Should be solid phase/ particle coated with recombinant and / or synthetic peptide antigens for Core, NS3, NS4 and NSS. 2. The assay should able to detect total antibodies (IgG, IgM & IgA) specific to HCV in human serum, plasma or whole blood. 3. Adequate documents detailing the principle, components, bio-safety methodologies, validity criteria interpretation of results, performance characteristics storage conditions, limitation of assays manufacturing & expiry dates should be provided with each kit. 4. The kit to be procured should have approval of the statutory authority in its country of origin. 5. The kit should have approval of the statutory authority in its country of origin. 6. In case of imported kits it should be registered and licensed under the provisions of drugs & cosmetics act and rules and/ or niedical devices rules 2017 in India. 7. In case of indigenous manufacturers should be licensed under the provisions of drugs & cosmetics act and rules and or medical devices rules 2017 issued by the competent authority defined under drugs and cosmetics act, 1940. 8. The kit should have minimum shelf- life of 5/6" or 12 months (whichever is more) at the port of discharge of consignees. 9. The total procedure time shall not be more than 20 minutes. 10. Assay should have Sensitivity 100% & specificity 100% or more with documentary evidence 11. The storage & transport temperature of the Kit should be 2-30°C. 12. The pack size should not be more than 50 tests wherein each test is individually evidence.		
191.	NES-22	**SyphilisAntibody (Rapid) detection kits** 1. The assay should be based on Rapid chromatographic immunoassay for qualitative detection of Antibodies (IgG, IgA & *IgM)* to TP in serum, plasma & whole Blood. 2. The assay should utilize recombinant Treponemal antigens i.e. Tp15, Tpl7, Tp47 against Syphilis. 3. The assay should be in card format. 4. Adequate documents detailing the principle components, bio- safety methodologies, validity criteria, interpretation of results, performance characteristics storage conditions, limitation of assays manufacturing & expiry dates should be provides with each kit. 5. The kit should have approval of the statutory authority in its country of origin. 6. In case of imported kits *it* should be registered and licensed under the provisions of Drugs & Cosmetics act and rules and/or medical	Each Piece	

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S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		devices rules 2017 in India. 7. In case of indigenous manufacturers should be licensed under the provisions of Drugs & cosmetics Act and rules and or medical devices rules 2017 issued by the competent authority defined under Drugs and cosmetics act, 1940. 8. The kit should have minimum shelf- life of 5/6th or 12 months (whichever is more) at the port of discharge of consignees. 9. Read result time should not be more than 20 minutes. 10. Assay should have Sensitivity 100% & specificity 99 %or more with documentary evidence. 11. The storage & transport temperature of the Kit should be 2-30°C. 12. The pack size should not be more than 50 tests wherein each test is individually		
192.	NES-23	**Malaria Antigen (Rapid) detection test** 1. Test should be based on Immunochromatographic assay. 2. The test should able to differentially detects Antigen of P. falciparum (HRP-2/ LDH) and Pan Plasmodia against P. falciparum, P. vivax, P. ovale, P. malariae (LDH) from human whole blood.in two different brand/lines. 3. The test band & control band should have different colours/same colours for differentiation. of control & Test band with respect to use of whole blood as a sample. 4. The membrane strip should be pre-coated with the antibodies specific to Histidine-rich protein II (HRP II) of P. falciparum on Pf test line and specific to the lactate Dehydrogenase (pLDH) Plasmodium species (P. falciparum, P. vivax, P. malariae, P. ovale) on Pan test line separately 5. The test should be in card format not in strip. 6. Adequate documents detailing the principle components, bio- safety methodologies, validity criteria, interpretation of results, performance characteristics storage conditions, limitation of assays manufacturing & expiry . dates should be provides with each kit. 7. The kit should have approval of the statutory authority in its country of origin. 8. In case of imported kits it should be registered and licensed under the provisions of Drugs & Cosmetics act and rules and/or medical devices rules 2017 in India. 9. In case of indigenous manufacturers should be licensed under the provisions of Drugs & cosmetics Act and rules and or medical devices rules 2017 issued by the competent authority defined under Drugs and cosmetics act, 1940. 10. The kit should have minimum shelf- life of 5/6th or 12 months (whichever is more) at the port of discharge of consignees. 11. Read result time should not be more than 30 minutes.	Each Piece	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		12. The storage & transport temperature of the kit should be 2-30°C. 13. The pack size should not be more than 50 tests wherein each test is individually packed.		
193.	NE-69	HBsAg (Rapid Test)- NE-69 1. Should be coated with monoclonal antibodies covering all subtypes and variants of HBsAg 2. The assay should be able to detect surface antigen to Hepatitis B virus. 3. Should be compatible with plasma and serum both. 4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit. 5. The kit should have approval of the statutory authority from the country of origin 6. In case of imported kits it should be registered and licensed by the DCG(I) 7. In case of indigenous manufactures should be licensed by the competent authourity/licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017 8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees. 9. The total procedure time shall not be more than 30 minutes. 10. The assay components should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls) which may be provided along with the kits if not a part of the kit. 11. The assay should have sensitivity of 100% and specificity of more than or equal to 98% as per the office order of MoHFW vide F. No 29/Misc./4/2016-DC(65) dated 13/6/2017 12. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control"or meant merely for checking the flow of reagents or integrity of antigens except except lateral flow technology General specifications 1. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8 °C. The cumulative time temperature indicator technology should be used on each kit and be per-qualified by WHO. 1. The pack size should not be more than 50 tests wherein each test is individually packed. 2. 8 Kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters 3. The kit will bw evaluated on the above parameters by the centers approved by the program The committee approved the specification of HBsAg(rapid test) 1.The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens General specifications 1. The manufacturer/authorized agent should ensure maintenance of could chain during storage and transport of kits at 2-8° C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO. 2. The pack size should not be more than 50 tests wherein each test is individually packed. 3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters 4. The kit will be evaluated on above perameters by the centers approved by the program The committee approved the specifications for Hepatitis B surface Antigen (Rapid Test)	Each Piece	
194.	NE-70	Anti-HCV Antibody (Rapid Test)- NE-70 1. Should utilize recombinant and /or synthetic peptide antigens for core, NS3, NS4 and NS5. 2. The assay should detect total anti HCV antibodies 3. Should be compatible with plasma and serum both. 4. Adequate documents detaling the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit. 5. The kit should have approval of the statutory authority from the country of origin 6. In case of imported kits it should be registered and licensed by the DCG (I) 7. In case of indigenous manufactures should be licensed by the competent authority/Licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017 8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees.	Each Piece	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		9. The total procedure time shall not be more than 30 minutes. 10. The assay component should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls) which may be provided along with the kits if not a part of the kit. 11. The assay should have sensitivity more than or equal to 99% and specificity of more than or equal to 98% as per the office order of MoHFW vide F. No 29/Misc./4/2016-DC (65) Dated 12/7/2017 12. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a " procedural control" or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology. General Specifications 1. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8 C. The cumulative time temperature indicator technology should be used on each kit and be per-qualified by WHO. 2. The pack size should not be more than 50 tests wherein each test is individually packed. 3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters 4. The kit will be evaluated on the above parameters by the centers approved by the program The committee approved the specification of Anti HCV antibody (rapid test) 11. The assay should have sensitivity more than or equal to 99% and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literature 12. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural contol" or meant merely for checking the flow of reagents or integrity of antigens General Specifications 1. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8° C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO. 2. The pack size should not be more than 50 tests wherein each test is individually packed. 3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters 4. The kit will be evaluated on the above parameters by the centers approved by the program The committee approved the specifications for Anti-HCV Antibody Kits (Rapid test)		

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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-16	Absorbable surgical suture sterilized surgical needled suture monofilament Polydioxanone Coated with Purest form of Triclosan violet 1/2 circle Taper Point, 17 mm needle, length 70cm size 3-0 [NRR-16]	12 Foils	Class C
16.	NRR-17	Absorbable surgical suture sterilized surgical needled suture monofilament Polydioxanone Coated with Purest form of Triclosan , violet 1/2 circle Taper Point RB-1, 17 mm needle, length 70cm size 4-0 [NRR-17]	12 Foils	Class C

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S.No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
17.	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
18.	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
19.	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
20.	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
21.	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
22.	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
23.	NRR-26	Monofilament Polyglyconate 1 150cm Gs-25 Loop, Green 48mm 1/2 Circle Taper Point	12 Foils	Class C
24.	NRR-27	Monofilament Polyglyconate 2-0, 75cm GREEN 26-30MM 1/2 Circle Taper Point	12 Foils	Class C
25.	NRR-28	Monofilament Polyglyconate 3-0, 75cm GREEN 20-26MM 1/2 Circle Taper Point	12 Foils	Class C
26.	NRR-29	Monofilament Polyglyconate 4-0, 75cm GREEN 17-20MM 1/2 Circle Taper Point	12 Foils	Class C
27.	NRR-30	Monofilament Synthetic Absorbable Suture Polydioxanone - Violet EP 3-0,70 Cm,1/2 Circle R.B.,20 Mm	12 Foils	Class C
28.	NRR-31	Monofilament Synthetic Absorbable Suture Polydioxanone - Violet EP 4-0,70 Cm,1/2 Circle R.B.,20 Mm	12 Foils	Class C
29.	NRR-32	Monofilament Synthetic Absorbable Suture Polydioxanone - Violet EP 5-0,70 Cm,1/2 Circle R.B.,13 Mm	12 Foils	Class C
30.	NRR-33	Monofilament Glycomer 1 90cm Gs-21 , Volet 37mm 1/2 Crcle Taper Pont	12 Foils	Class C
31.	NRR-34	Monofilament Glycomer 2-0 90cm Gs-21 , Volet 37mm 1/2 Crcle Taper Pont	12 Foils	Class C
32.	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
33.	NRR-36	Braided Coated Non Absorbable Suture USP 1-0 75 Cm X 2	12 Foils	Class C
34.	NRR-37	Braided Coated Non Absorbable Suture USP 2-0 75 Cm X 2	12 Foils	Class C
35.	NRR-38	Braided Coated Non Absorbable Suture USP 3-0 75 Cm X 2	12 Foils	Class C
36.	NRR-39	Silk Reel 4-0	12 Foils	Class C
37.	NRR-44	Braided Polyester Caoted With Silicon 2, 26MM 1/2 Circle RC 75cm	12 Foils	Class C

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38.	NRR-45	Braided Polyester Caoted With Silicon 5, 55MM 1/2 Circle RC 75cm	12 Foils	Class C
39.	NRR-54	Polypropylene Blue Monofilament, 2-0, 90 CM 1/2 Circle Round Body Double Needle 26 MM	12 Foils	Class C
40.	NRR-55	POLYPROPYLENE BLUE MONOFILAMENT USP 3/0,2,90 Cm,1/2 Circle Taper Point (Double Armed),26 Mm	12 Foils	Class C
41.	NRR-56	Polypropylene Blue Monofilament, 4-0, 75 Cm 1/2 Circle Round Body Double Needle 17 Mm	12 Foils	Class C
42.	NRR-57	POLYPROPYLENE BLUE MONOFILAMENT USP 5/0,1,90 Cm,1/2 Circle Taper Point (Double Armed),18 Mm	12 Foils	Class C
43.	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
44.	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	12 Foils	Class C
45.	NRR-60	Monofilament Polybuetester Coated With Polytribiolate 6-0 75CM 2XCV-1X36 , BLUE 9MM 3/8 Circle Taper Point	12 Foils	Class C
46.	NRR-61	Monofilament Polybuetester Coated With Polytribiolate 4-0 90CM 2XCV-23X36 , BLUE 17MM 1/2 Circle Taper Point	12 Foils	Class C
47.	NRR-62	Monofilament Polybuetester Coated With Polytribiolate 7-0 60CM 2XMV-175-8 , BLUE 8MM 3/8 Circle Taper Point	12 Foils	Class C
48.	NRR-63	Monofilament Polybuetester Coated With Polytribiolate 2-0 90CM 2XV-20X36 , BLUE 26MM 1/2 Circle Taper Point	12 Foils	Class C
49.	NRR-64	Monofilament Polybuetester Coated With Polytribiolate 3-0 90CM 2XV-20X36 , BLUE 26MM 1/2 Circle Taper Point	12 Foils	Class C
50.	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
51.	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,	12 Foils	Class C
52.	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
53.	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
54.	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
55.	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
56.	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
57.	NRR-73	Polyester Ethylene Terephthalate Nonabsorbable Surgical Suture Polyester Suture Is A Nonabsorbable,	12 Foils	Class C

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S.No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		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		
58.	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
59.	NRR-75	Absorbable Antibacterial Polydiaxonone Monofilament Taper Point Surgical suture Absorbable Antibacterial suture made up of Polydiaxonone coated with triclosan Voilet Monofilament 1/2 Circle Taper Point CT-1 40 mm needle 90 cm Suture size 1 [NRR-75]	12 Foils	Class C
60.	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
61.	NRR-80	Non-Absorbable Surgical Suture Black Braided Silk 1-0 RC 3/8 Circle 45 Mm 76 Cm	12 Foils	Class C
62.	NRR-81	Non-Absorbable Surgical Suture Black Braided Silk 5-0 RC 3/8 Circle 12 Mm 76 Cm	12 Foils	Class C
63.	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
64.	NRR-83	Non-Absorbable Surgical Suture Black Braided Silk 6-0 RC MP 3/8 Circle 8 Mm	12 Foils	Class C
65.	NRR-85	Braided Coated Polyglactin Absorbable Suture Polyglactin 910 -Undyed 2-0, 1/2 Circle Taperpoint, 36 Mm,100 Cm	12 Foils	Class C
66.	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
67.	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
68.	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
69.	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
70.	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
71.	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
72.	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
73.	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

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S.No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
74.	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
75.	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
76.	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
77.	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

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	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
1	2	3		4	5
1	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	

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Sr. No	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				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.**

Signature valid

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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,	

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S.N.	Details of the requirement	Remark
	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	

S.N.	Details of the requirement	Remark
	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.	

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S.N.	Details of the requirement	Remark
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 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 ;	

S.N.	Details of the requirement	Remark
	(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 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:

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 [illegible].41:10 IST
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ANNEXURE –IX

(Ref: Clause no. 9)

AGREEMENT

This Deed of Agreement is made on this _____day of_____ 2025 by M/s._____ represented by its Proprietor/ Managing partner /Managing Director having its laboratory Premises at _____ (hereinafter referred to as "Service provider" which term shall include its successors, representatives, heirs, executors and administrators unless excluded by the Contract) on one part and Rajasthan Medical Services Corporation Ltd, represented by its Executive Director (P) having is office at SwasthyaBhawan, TilakMarg, C-Scheme, Jaipur (hereinafter referred to as "The Purchaser" which term shall include its successors, representatives, executors assigns and administrator unless excluded by the Contract) on the other part.

Whereas the Service provider has agreed to test the Surgical and Suture for RMSC with specifications mentioned in the Schedule attached here to and mentioned at the prices noted there

in and in the manner and under the terms and conditions here in after mentioned and where as the Service provider has deposited with the Purchaser a sum of Rs_____(Rupees only) as Performance Security Deposit for the due and faithful performance of this Agreement, to be forfeited in the event of the Service provider failing duly and faithfully to perform it. Now these presents witness that for carrying duly and faithfully to perform it. Now these presents witness that for carrying out the said Agreement in this behalf into execution the Service provider and the Purchaser do hereby mutually covenant, declare, contract and agree each of them with the other of them in the manner following, that is to say,

The term "Agreement", wherever used in this connection, shall mean and include the terms and conditions including amendments contained in the invitation to tender floated for the Empanelment of Analytical Testing Laboratories for the test and Analysis of Surgical/suture/medical device for Rajasthan Medical Services Corporation Ltd **F.02(188)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2025/** Dated:- the instruction to Bidders, the conditions of Bid, acceptance of Bid, particulars hereinafter defined and those general and special conditions that may be added from time to time.

1. (a) The Agreement is for the test by the Service provider to the Purchaser of the testing of Surgical/suture/medical device and Medicines specified in the Schedule attached here to at process noted against each therein on the terms and conditions set forth in the Agreement.

   (b) The Agreement with empanelled laboratories will remain valid up to ----------
   This may be further extended for a further period of three months with mutual consent.

TERMINATION OF CONTRACT ON BREACH OF CONDITION

1. (a) In case the Service provider fails or neglects or refuse to faithfully perform any of the Covenants on his part herein contained, it shall be lawful for the Purchaser to forfeit the amount deposited by the Service provider as Performance Security and cancel the Contract.

   (b) In case the Service provider fails, neglects, or refuse to observe, perform, fulfill and keep, all or any one or more or any part of any one of the Covenants, stipulation and provisions herein contained, it shall be lawful for the Purchaser on any such failure, neglect or refusal, to put an end to this Agreement and thereupon every article, cause and thing herein contained on the part of the Purchaser shall cease and be void, and in case of any damage, loss, expenses, difference in cost or other moneys from out of any moneys for the time being payable to the Service provider under this and/or any other Contract and in case such last mentioned moneys are insufficient to cover all such damages, losses, expenses, difference in cost and other moneys as aforesaid, it shall be lawful for the Purchaser to appropriate the Performance Security made by the Service provider as herein

before mentioned to reimburse all such damages, losses, expenses, difference in cost and other money as the Purchaser shall have sustained, incurred or been put to by reason of the Service provider having been guilty of any such failure, negligence or refusal as aforesaid or other breach in the performance of this Contract.

(c) If at any time during the course of the Contract, it is found that any information furnished by the Service provider to the Purchaser, either in his Tender or otherwise, is false, the Purchaser may put an end to the Contract/Agreement wholly or in part and thereupon the provisions of Clause (a) above shall apply.

2. The Purchaser reserves the right to terminate, without assigning any reasons therefore the Contract/Agreement either wholly or in part without any notice to the Service provider. The Service provider will not be entitled for any compensation whatsoever in respect of such termination of the Contract/Agreement by the Purchaser.

NOTICE ETC, IN WRITING

3. All Certificates or Notice or orders for time or for extra, varied or altered supplies which are to be the subject of extra or varied charges whether so described in the Agreement or not, shall be in writing, and unless in writing, shall not be valid, binding or be of any effect whatsoever.

SERVICE PROVIDER NOT HAVE ANY INTEREST IN THE OFFICERS CONCERNED AND SUBORDINATES

4. The Service provider shall not be in any way interested in or concerned directly or indirectly with, any of the Officers, Subordinate or Servants of the Purchaser. In any trade, business or transactions nor shall the Service provider give or pay or promise to give or pay any such Officer, Subordinate or Servant directly or indirectly any money or fee or other consideration under designation of "Custom" or otherwise; nor shall the Service provider permit any person or persons whomsoever to interfere in the management or performance hereof under power of attorney or otherwise without the consent in writing the consent in writing of the Purchaser obtained in first hand.

BANKRUPTCY OF THE SERVICE PROVIDER

5. In case the Service provider at any time during the continuance of the Contract becomes bankrupt or insolvent or commits any act of bankruptcy or insolvency under the provisions of any law in that behalf for the time being in force, or should compound with his creditors, it shall be lawful for the Purchaser to put an end to the Agreement, and thereupon every article, clause and thing herein contained to be operative on the part of the Purchaser, shall cease and be void and the Purchaser shall have all the rights and remedies given to him under the preceding clauses.

SERVING OF NOTICE ON SERVICE PROVIDER

1. All notice 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 Service provider if delivered to him or left at his premises, place of business or abode.
2. And it is hereby agreed and declared between the parties hereto that in case any question of dispute arises touching the construction or wording of any of clause herein contained on the rights, duties, liabilities of the parties hereto or any other way, touching or arising out of the presents, the decision of the Managing Director, Rajasthan Medical Services Corporation Ltd in the matter shall be final and binding.
3. All disputes arising out of this agreement and all questions relating to the interpretation of this agreement shall be decide by the Govt. and the decision of the Govt. shall be final.

SERVICER PROVIDER
(Signature, Name & Full Address)

Executive Director (Procurement),
RAJASTHAN MEDICALSERVICES CORPORATION LTD.

Witness (Signature, Name & Full Address)

1.
2.

Signature valid
Digitally signed by Manoj Kumar
Designation: Executive Director
Date: 2025.04.08 17:41:10 IST
Reason: Approved