



Ref. No.: F.02(89)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2021/86 Dated
:23.03.2021

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
(A Govt. of Rajasthan Undertaking)
Gandhi Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India
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**E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING
LABORATORIES FOR THE TEST AND ANALYSIS OF
SURGICAL & SUTURES (Ending on 31.03.2023)**



!! सर्वे सन्तु निरामया:!!

LAST DATE OF SUBMISSION OF ONLINE BIDS	27.04.2021at 6.00 PM
DATE AND TIME OF OPENING OF ONLINE TECHNICAL BIDS	28.04.2021 at 11.00 AM

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Gandhi Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India

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F.02(89)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2021/86 Dated :23.03.2021

Notice Inviting E-Bids

E-bids are invited up to **6.00 PM of 27.04.2021** for THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF SURGICAL & SUTURES (NIB 01/21). Details of NIB may be seen in the Bidding Documents at our office or at the website of State Public procurement Portal <http://sppp.raj.nic.in>, (UBN MSC2021SLRC00144) www.dipronline.org, <http://eproc.rajasthan.gov.in>, www.rmhc.health.rajasthan.gov.in and may be downloaded from there.

Note:- If any amendment is carried out in the tender specifications and terms & conditions following pre-bid meeting, the same will be uploaded on the *Departmental website* www.rmhc.health.rajasthan.gov.in, sppp.raj.nic.in and <https://eproc.rajasthan.gov.in>. In case any inconvenience is felt, please contact on telephone number i.e. 0141-2228064

**Executive Director (Procurement)
RMSCL**

RAJASTHAN MEDICAL SERVICES CORPORATION LTD. RAJASTHAN

**E-BID FOR THE EMPANELMENT OF ANALYTICAL
TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF
SURGICAL & SUTURES
(Ending on 31.03.2023)**

Bid Reference	:	F.02(89)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2021/86 Dated :23.03.2021
Pre- bid conference	:	31.03.2021 at 11.00 A.M. (RMSC meeting Hall)
Date and time for downloading bid document	:	24.03.2021 from 6.00 PM
Last date and time of submission of online bids	:	27.04.2021 up to 6.00 PM
Date and time of opening of Online technical bids	:	28.04.2021 at 11:30 AM
Cost of the Bid Document	:	Rs. 2000/-
RISL Processing Fees	:	Rs. 1000/-
EMD	:	Rs. 20000/-

**RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
RAJASTHAN**

**E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING
LABORATORIES FOR THE TEST AND ANALYSIS OF
SURGICAL & SUTURES (Ending on 31.03.2023)**

“CONFIDENTIALITY IS THE ESSENCE OF THIS BID”

**1. LAST DATE FOR RECEIPT OF BIDS, BID FEES, EMD, 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 27.04.2021** By The Rajasthan Medical Services Corporation Ltd, For the Empanelment of Analytical Testing Laboratories for the Test and Analysis Of SURGICAL & SUTURES (**Ending on 31.03.2023**) 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 for another period of 30 days. The Bidder may refuse extension of bid validity without forfeiting the Earnest Money deposit. No refund of tender fee is claimable under any circumstances to any of the bidder.
- c) The e-Bids will be received on web-portal of e-procurement of GoR. Every Bidder will be required to pay the Bid form fee Rs. 2000.00 for downloaded from the website, Bid Security **Deposit / Form of Bid securing Declaration as per Annexure X** as applicable in Bid condition no. **6** and processing fee of Rs.1000.00 of R.I.S.L. These fees are to be paid through three separate prescribed challans (format enclosed in Annexure- I) in any branch of the Punjab National Bank Account no. 2246002100024414 & IFSC Code no. PUNB0224600 throughout country upto 27.04.2021 or through D.D. / bankers cheque in favour of M.D. RMSCL (Bid document fees and Bid security / **Form of Bid securing Declaration as per Annexure X**), M.D. RISL (Bid processing fees) physically in the office of RMSC by 6.00 PM on 27.04.2021 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. **In the absence of Bid document fees and processing fees and Bid Security Deposit / Form of Bid securing Declaration as per Annexure X the Bids will be rejected and will not be opened.**

2. Eligibility Criteria for Empanelment :-

- (1) Testing Laboratories should have valid Approval for carrying out test on drugs\surgical & sutures under the Drugs and Cosmetics Act, 1940 and Rules there under. Three years standing in the test & analysis of **Surgical & Sutures/drugs/chemicals or food** items and the lab shall be entitled for empanelment for the categories of items for which lab is having approval. Bid is invited from NABL approved Testing Laboratories situated in India.
- (2) **The laboratory should be GLP compliant under the provisions of Drugs and Cosmetics Act, 1940 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 surgical and sutures. GLP certificate should be clear, it should not contain ambiguous expressions, like ‘by and large’.**
- (3) The laboratory should have an average annual turnover of **not less than Rs. 1 Crore** for past preceding three years (**2016-17, 2017-18 & 2018-19 or 2017-18, 2018-19 & 2019-20**).(ANEXURE-II)
- (4) The lab should have undertaken test and analysis of surgical & sutures at 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) **EMD (Bid security) forfeiture**
 - (iii) **Agreement rejection**
 - (iv) **S.D. 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) The bidder must follow Test Parameter given for individual item in Annexure – VIII.

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 to be testing at Annexure-VII). The bidder has to mentioned type of test for each item to be carried out by him, the filled up annexure VIII to be submitted with technical bid.

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

- b. The bidders shall submit/upload scanned copy of all the challans, D.D./ BC / **Form of Bid securing Declaration for bid security as per Annexure X**, annexed with Technical Bid in proof of deposition/ submission of Bid document fees, RISL processing fee and Bid security in case deposited in any branch of PNB throughout country. The required Bid Security Deposit / Bid document fees/ RISL fee may be in form of physical D.D. / BC and should be in favour of M.D. RMSCL (bid document fees and Bid Security Deposit) and M.D. RISL (bid processing fees).
- c. Attested Photocopy of Analytical approval duly renewed up to date, issued by the State Licensing Authority.
- d. **Compliance of Schedule L-1 of Drugs & Cosmetics Rules, 1945 (GLP certificate) and Copy of NABL accreditation with scope for testing of Surgical & Sutures.**
- e. Documentary evidence of having analyzed Surgical & Sutures/ Drugs, chemicals, foods and other items for the last three years with a statement in the proforma as given in Annexure III.

- f. Attested copy of certificate of registration for service tax.
- g. Non- Conviction Certificate by the State Licensing Authority/ competent authority.
- h. Annual turnover statement for last 3 year i.e. **2016-17, 2017-18 & 2018-19 or 2017-18, 2018-19 & 2019-20** (ANEXURE-II) certified by the practicing Chartered Accountant.
- i. Copies of the Balance Sheet and Profit and Loss Account for three years i.e **2016-17, 2017-18 & 2018-19 or 2017-18, 2018-19 & 2019-20** duly audited or certified by the practicing Chartered Accountant.
- j. The following information in the form given in Annexure IV (a) to IV(d).
 - a) The list of permanent technical qualified personnel employed in the laboratory with proof of their qualifications and relevant approvals.
 - b) The list of sophisticated instruments available in the laboratory.
 - c) Micro Biological facilities available in the laboratory.
- d. List of Reference Samples along with their date of procurement and quantities.
- e. In the case of Non- Pharmacopoeial Products the Method of Analysis Should be appended to the Report, especially if the sample is declared as “not of standard quality”.
- k. A declaration in the proforma given in Annexure V duly signed and Notarized.
- l. Details of Laboratory in Annexure – VI.
- m. A copy of PAN issued by Income Tax Department.
- n. Documentary evidence for the constitution of the company / concern.
- o. At any time prior to opening of price bid RMSC either at their own initiate or in response to clarification requested by prospective tender, may modify tender by issuing an amendment. Such amendments shall be loaded on E-Proc site and will be the part of tender.
- p. Bidders has to fill up the checklist Anne – IX. the infrastructure and testing facilities available in the lab.

4 PRICE BID :

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

bidder is liable to be rejected for this bid. Bidders are allowed to enter the bidder name and values only. The bidder should quote rate for the complete tests as applicable to the item. The rate for sterility test for sterile products should also be quoted separately at last entry of BOQ. Any type of uncalled for clarification on prices and or rebates shall not be accepted.

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

~~It is further clarified that if a bidder does not fill the IGST, CGST, SGST column, or does not fill any other column, than the bid shall be treated as uncompleted and liable to be rejected prima facie.~~

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 EARNEST MONEY DEPOSIT (BID SECURITY)

The Bid Security shall be Rs. 20,000/- paid through separate prescribed challan (format enclosed in Annexure-I) in any branch of the Punjab National Bank Account no. 2246002100024414 & IFSC Code no. PUNB0224600 throughout country up to 27.04.2021 or through D.D. / bankers cheque in favor of M.D. RMSCL physically in the office of RMSCL / **Form of Bid securing Declaration for bid security as per Annexure X** on or before 27.04.2021 upto 6.00 PM. Bid Security Deposit in any other form will not be accepted.

The Bids submitted without sufficient EMD will be summarily rejected. The EMD 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 are exempted for EMD deposition on producing the certificate issued by the competent authority.

7 GENERAL CONDITIONS

1. The details of the surgical & sutures, to be analysed shall be given in **Annexure VII**.

2. The Bidder should quote the rates for complete analysis of each product and name of test to be performed, methodology to be used for each test should be mentioned in **Annexure-VII. However wherever rates for individual test are demanded, they should be furnished accordingly in BOQ. Wherever test are prescribed and their name and methodology for testing are not stated, such lab will not be considered responsive testing for such item.**
3. The rates quoted should be exclusive of taxes.
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 RMSCL, then Samples of its own manufacturing unit shall not be sent to its empanelled laboratory for testing.
6. The laboratory will not be permitted to outsource any test from other laboratory.
7. RMSCL shall have the right to cause the laboratory to be inspected by the members of its technical committee before opening of price bid and subsequently as and when considered appropriate and based on the finding, the Bidder may be disqualified or de-empanelled, as the case may be.
8. Conditional tender will not be accepted and rejected immediately.

8. ACCEPTANCE OF BID

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

9. AGREEMENT

1. **The agreement with empanelled laboratories will remain valid up to 31.03.2023. If required period of contract can be extended upto 3 months same rate, terms and condition without any prior consent and shall be binding on approved bidder.**
2. RMSCL will issue letters of Intent (LOIs) to successful bidders and bidders who are empanelled will have to execute an agreement on a non-judicial stamp paper of value **Rs. 1000 /-** (Stamp duty to be paid by the Bidder), in favour of Managing Director, Rajasthan Medical Services

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

3. The Bidder shall not, at any time, assign, sub-let or make over the contract or the benefit therefore or any part thereof to any person or persons whatsoever.
4. All notices or communication relating to, or arising out of this agreement or any of the terms thereof shall be considered duly served on or given to the Bidder if delivered to him or left at the premises, places of business or abode.

10. PERFORMANCE SECURITY

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

11. COMPLETE ANALYSIS & REPORTING CONDITIONS

1. (a) On empanelment and entrustment of the job, the Analytical Laboratory should
furnish the test reports within:
I. 10 days from the receipt of the sample in case of (non – sterile products)
II. 21 days from the receipt of the sample of surgical & sutures requiring test for sterility.
b) All the tests mentioned in IP/BP/USP/Drugs & Cosmetics Act. etc. including addendus, (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 any surgical& suture is not included in the pharmacopeia at the time of bid opening and letter on it is including in any pharmacopeia the surgical& suture should be tested as per pharmacopeia specification.
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 placebo or standard test procedure of any product is required the same should be demanded within 48 hours with return request. Period lapsed/taken in providing placebo or standard testing procedure will be condoned from prescribed time limit for that sample.
 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 successful 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 tax on it will be along with Tax at the prevailing rate as applicable at the time of payment.

13. PENALTIES

1. If the successful Bidder fails to execute the agreement and payment of security deposit within the time specified or withdraws the BID after intimation of the acceptance of the BID has been sent to or owing to any other reasons, he is unable to undertake the contract, the empanelment will be cancelled and the Earnest Money Deposit deposited by the Bidder shall stand forfeited in favour of the Rajasthan Medical Services Corporation Limited. Such Bidder(s) will also be liable for all damages sustained by the Rajasthan Medical Services Corporation Limited due to of breach of BID conditions. Such damages shall be assessed by the Managing Director, Rajasthan Medical Services Corporation Limited whose decision shall be final.

2. Non performance of any BID or empanelment conditions will disqualify a laboratory to participate in the BID for the period as decided by RMSCL.
3. If it is revealed that the analytical Laboratory is involved in any form of fraud and collusion with the suppliers of Rajasthan Medical Services Corporation Limited, the Analytical Laboratory will be black listed for a period considered suitable. The Bidders shall also be liable for action under criminal law and the matter will be notified to the concerned Director of Drugs Control for suitable action against them under Drugs & Cosmetics Act & Rules.
4. The Managing Director, Rajasthan Medical Services Corporation Limited will be at liberty to terminate without assigning any reasons, the empanelment of any laboratory either wholly or in part at one month's notice. The Bidder will not be entitled for any compensation whatsoever in respect of such termination.
5. In all matters pertaining to the BID, the decision of the Managing Director, Rajasthan Medical Services Corporation Limited shall be final and binding.
6. (i) If the laboratory requires an extension in time for submission of test report, on account of occurrence of any hindrance he shall apply in writing for extension on occurrence of hindrance but not after the stipulated date of *furnishing the test report*.
(ii) The Executive Director (QC)/ Drug Controller/ADC (QC) may extend the testing period with or without liquidated damages in case they are satisfied that the delay in the submission of test reports is on account of any hindrances, he shall apply in writing for extension on occurrence of hindrance but not after the stipulated date of submission of report. Reasons shall be recorded.
(iii) **Extension in testing period:-** In case of extension in the testing period with liquidated damages the recovery shall be made on the basis of following percentages of *testing charges* which the Bidder has failed to submit:-
 - (a) Delay upto one fourth period of the prescribed testing period; 2.5%
 - (b) Delay exceeding one fourth but not exceeding half of the prescribed testing period; 5%

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

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

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

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

14. CORRECTION OF ARITHMETIC ERRORS:

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

- (i) If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail and the total price shall be corrected, unless in the opinion of the Procuring Entity there is an obvious misplacement of the decimal point in the unit price, in which case the total price as quoted shall govern and the unit price shall be corrected;
- (ii) If there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected; and.
- (iii) If there is a discrepancy between words and figures, the amount in words shall prevail, unless the amount expressed in words is related to an arithmetic error, in which case the amount in figures shall prevail subject to clause (a) and (b) above.

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

15. GRIEVANCE REDRESSAL DURING EMPANELMENT PROCESS:

The Designation and address of the First Appellate Authority is Special_ Secretary/ Secretary, Medical, Health & Family Welfare, Govt. of Rajasthan.

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

i. Filling an appeal

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

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

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

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

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

iv. Appeal not to lie in certain cases

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

- (a) Determination of need of empanelment;
- (b) Provision limiting participation of Bidders in the Bid process; (c) The decision of whether or not to enter into negotiations;
- (d) Cancellation of a empanelment process;
- (e) Applicability of the provisions of confidentiality.

v. Form of Appeal

- (a) An appeal under Para (1) or (3) above shall be in the annexed Form along with as many copies as there are respondents in the appeal.
- (b) Every appeal shall be accompanied by an order appealed against, if any, affidavit verifying the facts stated in the appeal and proof of payment of fee.
- (c) Every appeal may be presented to First Appellate Authority or Second Appellate Authority, as the case may be, in person or through registered post or authorised representative.

vi. Fee for filling appeal

- (a) Fee for first appeal shall be rupees two thousand five hundred and for second appeal shall be rupees ten thousand, which shall be non-refundable.
- (b) The fee shall be paid in the form of bank demand draft or banker's cheque of a Scheduled Bank in India payable in the name of Appellate Authority concerned.

vii. Procedure for disposal of appeal

- (a) The First Appellate Authority or Second Appellate Authority, as the case may be, upon filling of appeal, shall issue notice accompanied by copy of appeal, affidavit and documents, if any, to the respondents and fix date of hearing.
- (b) On the date fixed for hearing, the First Appellate Authority or Second Appellate Authority, as the case may be, shall,
 - (i) Hear all the parties to appeal present before him; and
 - (ii) Peruse or inspect documents, relevant records or copies thereof relating to the matter.

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

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

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

Any person participating in a empanelment process shall-

- a) Not offer any bribe, reward or gift or any material benefit either directly or indirectly in exchange for an unfair advantage in procurement process or to otherwise influence the procurement process;
- b) Not misrepresent or omit misleads or attempts to mislead so as to obtain a financial or other benefit or avoid an obligation;
- c) Not indulge in any collusion, Bid rigging or any-competitive behaviour to impair the transparency, fairness and progress of the procurement process;
- d) Not misuse any information shared between the procuring Entity and the Bidders with an intent to gain unfair advantage in the procurement process;
- e) Not indulge in any coercion including impairing or harming or threatening to do the same, directly or indirectly, to any part or to its property to influence the procurement process;
- f) Not obstruct any investigation or audit of a procurement process;
- g) Disclose conflict of interest, if any; and
- h) Disclose any previous transgressions with any Entity in India or any other country during the last three years or any debarment by any other procuring entity.

17. Conflict of interest:-

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

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

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

- a. Have controlling partners/shareholders in common; or
 - b. Receive or have received any direct or indirect subsidy from any of them;
- or
- c. Have the same legal representative for purposes of the Bid; or
 - d. Have a relationship with each other, directly or through common third parties, that puts them in a position to have access to information about or influence on the Bid of another Bidder, or influence the decisions of the Procuring Entity regarding the bidding process; or
 - e. The Bidder participates in more than one Bid in a bidding process. Participation by a Bidder in more than one Bid will result in the disqualification of all Bids in which the Bidder is involved. However, this does not limit the inclusion of the same subcontractor, not otherwise participating as a Bidder, in more than one Bid; or
 - f. The Bidder or any of its affiliates participated as a consultant in the preparation of the design or technical specification of the Goods, Works or Services that are the subject of the Bid; or
 - g. Bidder or any of its affiliates has been hired (or is proposed to be hired) by the Procuring Entity as engineer-in-charge/ 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.

Managing Director
Rajasthan Medical Services Corporation

Annexure - 1

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

Bank Copy

punjab national bank

DIST. NO.

Branch

Institute Name

Institute ID

Date of Deposit

DD MM YY

Rajasthan Medical Services Corporation, Jaipur

RMSCJ - A/c No. 2246002100024414

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 ₹	0	0	0	0	-	0	0
Commission ₹	0	0	0	0	-	0	0
Total amount ₹	0	0	0	0	-	0	0

Amount (in words): ₹

Name of the Depositor _____
 Signature _____
 Address for communication _____

Acknowledgement

For Bank use only

Cashier/Officer

Customer Copy

punjab national bank

DIST. NO.

Branch

Institute Name

Institute ID

Date of Deposit

DD MM YY

Rajasthan Medical Services Corporation, Jaipur

RMSCJ - A/c No. 2246002100024414

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 ₹	0	0	0	0	-	0	0
Commission ₹	0	0	0	0	-	0	0
Total amount ₹	0	0	0	0	-	0	0

Amount (in words): ₹

Name of the Depositor _____
 Signature _____
 Address for communication _____

Acknowledgement

For Bank use only

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 Lakhs (Rs)	
1	2016-17		
2	2017-18		
3	2018-19		
Total		Rs.	Lakhs
Average turnover per annual		Rs.	Lakhs

OR

S.No.	Years	Turnover in Crore (INR.)	
1	2017-18		
2	2018-19		
3	2019-20		
Total		Rs.	Crore
Average turnover per annual		Rs.	Crore

Date:

Seal:

Signature of Auditor/
Chartered Accountant
(Name in Capital)

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

Name of the Laboratory :

Address: _____

Types of Samples Analysed	No. of Samples Analysed during (2016-17, 2017-18 & 2018-19 or 2017-18, 2018-19 & 2019-20)
---------------------------	-------------------------------------------------------------------------------------------------

01. Surgicals (Specify item names)

02. Sutures (Specify types)

03. Implants

04. Devices

Signature :

Date :

Name of the Lab :

Office Seal :

PERSONNEL IN QC DEPARTMENT

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 :

Name of the Lab :

Office Seal :

**LIST OF SOPHISTICATED EQUIPMENT/INSTRUMENT/APPARATUS
AVAILABLE IN THE LAB**

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

Signature :

Name of the Lab :

Date :

Official Seal:

FACILITIES IN THE MICROBIOLOGICAL SECTION

I. LIST OF STOCK CULTURES AVAILABLE

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

Signature :

Name of the Lab :

Date :

Official Seal:

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

**LIST OF REFERENCES SAMPLES ALONG WITH THEIR DATE OF
PROCUREMENT AND QUANTITIES**

Signature :

Name of the Lab :

Date :

Official Seal:

Affidavit

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

ANNEXURE – V
Ref. Clause No: 3(k)

DECLARATION FORM

1. I (Name of the Bidder) S/O _____, Age _____, resident of _____, am proprietor /Partner/Director having our office at _____ and the approved Surgical & Sutures 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. (Ending on 31.03.2023) 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 for which Price Bid have been submitted by me/us in Cover B and permission on Form 37 have been obtained for testing of these items from State Licensing Authority where ever applicable.
3. That the approval to test drugs/surgical & sutures have been obtained on Form 37 bearing No. _____ which is valid/renewed up to _____.
4. That the Bidder firm is a proprietorship/Partnership/Pvt. Ltd./Ltd. firm and following are the other partners/directors:-

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

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

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

That I/We have carefully read all the conditions of bid in Ref. No.: F.02(89)/RMSCL/LAB EMPANELMENT(S&S)/NIB-01/2021/86 Dated :23.03.2021

6. For the empanelment of analytical testing laboratories for the test and analysis of SURGICAL &SUTURES (Ending on 31.03.2023) for Rajasthan medical services corporation and accept all conditions of bid, including amendments if any.
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 taxes payable to the Union and the State Government or any local authority as specified in the Bidding Document;
 - c. I/we are not insolvent, in receivership, bankrupt or being wound up. not have my/our affairs administered by a court or a judicial officer, not have my/our business activities suspended and not the subject of legal proceedings for any of the foregoing reasons;
 - d. I/we do not have, and our directors and officers not have, been convicted of any criminal offence related to my/our professional conduct or the making of false statements or misrepresentations as to my/our qualifications to enter into a procurement contract within a period of three years preceding the commencement of this procurement process, or not have been otherwise disqualified pursuant to debarment proceedings;
 - e. I/we do not have a conflict of interest as specified in the Act, Rules and the Bidding Document, which materially affects fair competition;

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

PAN of the Lab:- -----

9. E mail address :- -----

10. Bank detail for e banking :-

Name of account holder

(Affidavit Page2)

Full name of Bank with Branch

A/c no. with full digits.....

IFSC code

(Deponent)

Signature :

Date :

Name of the Lab :

Office Seal :

Verification

I.....S/o.....(Designation).....

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

(Name of Deponent & Signature)

ATTESTED BY NOTARY PUBLIC

(I)

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

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

SUTURES LIST

S.No.	Code No.	Name of approved item (s) with specification	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 (1/2 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 (1/2 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 (1/2 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 (1/2 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 R Cutting 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
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

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Class As per Medical Device Rules 2017
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) (3/8 Cir slim blade Cutting Needle 15mm Length 70 cm)	5/0	12 Foils	Class C
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

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Class As per Medical Device Rules 2017
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
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 (1/2 Cir	1	12 Foils	Class C

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Class As per Medical Device Rules 2017
		Reverse Cutting, 45 mm Needle length 100 cm)			
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
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 POLYESTER, GREEN/WHITE or BLUE/WHITE Polybutylate / Silicon Coated Polyester 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 POLYESTER, GREEN/WHITE or BLUE/WHITE Polybutylate / Silicon Coated Polyester 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 POLYESTER, GREEN/WHITE or BLUE/WHITE Polybutylate / Silicon Coated Polyester 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 needed suture Polybutylate / Silicon Coated with Polyester 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 needed suture Polybutylate / Silicon Coated with Polyester 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 POLYESTER, GREEN/WHITE or BLUE/WHITE Coated Polyester 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,	Size 2/0	12 Foils	Class C

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Class As per Medical Device Rules 2017
		MONOFILAMENT SUTURES (1/2 Circle Oval RB Needle 26mm Needle, Suture Length of 70cm)			
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 POLYGLECAPRONE / Polyglyconate, MONOFILAMENT SUTURES (3/8 Circle Cutting24- 26mm Needle, Suture Length of 70-90cm)	3/0	12 Foils	Class C
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 NEEDED 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 NEEDED 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 NEEDED 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

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Class As per Medical Device Rules 2017
73.	R-76	Absorbable Surgical Suture (Sterile Catgut), Needled Suture Chromic (3/8 Cir R Cutting Needle 16mm, Length 76 cm)	5/0	12 Foils	Class C
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 R Cutting Needle 19mm Length 76 cm)	4/0	12 Foils	Class C

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

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 sterilized.	Piece	Class C
2.	S-2	Absorbent Cotton Wool IP 500 gm	Packet	Class B
3.	S-3	Asepto Syringe with Transparent Bulb Sterile, 60 ml	Piece	ND
4.	S-4	Blood Administration Set / Blood Transfusion Set <ul style="list-style-type: none"> • 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
5.	S-5(a)	Disposable Sterile Surgical Rubber Gloves Size 6 ½ Inches <ul style="list-style-type: none"> • 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
6.	S-5(b)	Disposable Sterile Surgical Rubber Gloves Size 6 ½ Inches <ul style="list-style-type: none"> • 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
7.	S-6(a)	Disposable Sterile Surgical Rubber Gloves Size 7 Inches <ul style="list-style-type: none"> • 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
8.	S-6(b)	Disposable Sterile Surgical Rubber Gloves Size 7 Inches <ul style="list-style-type: none"> • 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
9.	S-7(a)	Disposable Sterile Surgical Rubber Gloves Size 7½ Inches <ul style="list-style-type: none"> • 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
10.	S-7(b)	Disposable Sterile Surgical Rubber Gloves Size 7 ½ Inches <ul style="list-style-type: none"> • 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 	Pair	ND

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<ul style="list-style-type: none"> 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)		
11.	S-8(a)	Suction Catheter, Sterile. Size: FG 5 (For use in respiratory tract) <ul style="list-style-type: none"> 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 ISO 8836:2014 	Each Piece	Class B
12.	S-8(b)	Suction Catheter, Sterile. Size: FG 6 (For use in respiratory tract) <ul style="list-style-type: none"> 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 ISO 8836:2014 	Each piece	Class B
13.	S-8(c)	Suction Catheter, Sterile. Size: FG 8 (For use in respiratory tract) <ul style="list-style-type: none"> 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 ISO 8836:2014 	Each piece	Class B
14.	S-8(d)	Suction Catheter, Sterile. Size: FG 10 (For use in respiratory tract) <ul style="list-style-type: none"> 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 ISO 8836:2014 	Each piece	Class B
15.	S-8(e)	Suction Catheter, Sterile. Size: FG 12 (For use in respiratory tract) <ul style="list-style-type: none"> 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 ISO 8836:2014 	Each piece	Class B
16.	S-8(f)	Suction Catheter, Sterile. Size: FG 14 (For use in respiratory tract) <ul style="list-style-type: none"> 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 ISO 8836:2014 	Each piece	Class B
17.	S-8(g)	Suction Catheter, Sterile. Size: FG 16 (For use in respiratory tract) <ul style="list-style-type: none"> 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 ISO 8836:2014 	Each piece	Class B
18.	S-8(h)	Suction Catheter, Sterile. Size: FG 18 (For use in respiratory tract) <ul style="list-style-type: none"> 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.) 	Each piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<ul style="list-style-type: none"> As per ISO 8836:2014 		
19.	S-8(i)	Suction Catheter, Sterile. Size: FG 20 (For use in respiratory tract) <ul style="list-style-type: none"> 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 ISO 8836:2014 	Each Piece	Class B
20.	S-8(j)	Suction Catheter, Sterile. Size: FG 22 (For use in respiratory tract) <ul style="list-style-type: none"> 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 ISO 8836:2014 	Each Piece	Class B
21.	S-9(a)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size 8 FG <ul style="list-style-type: none"> 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
22.	S-9(b)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size10 FG <ul style="list-style-type: none"> 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
23.	S-9(c)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size16 FG <ul style="list-style-type: none"> 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
24.	S-9(d)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size18 FG <ul style="list-style-type: none"> Made of Silicone elastomer bonded with Latex Should have hard plastic valve 	Each Piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<ul style="list-style-type: none"> • 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 		
25.	S-9(e)	<p>Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size20 FG</p> <ul style="list-style-type: none"> • 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-9(f)	<p>Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size22 FG</p> <ul style="list-style-type: none"> • 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
27.	S-9(g)	<p>Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size 24 FG</p> <ul style="list-style-type: none"> • 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
28.	S-10 (a)	<p>Infant Feeding Tube Size:10FG length 50 cm (min.)</p> <ul style="list-style-type: none"> • 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
29.	S-10 (b)	<p>Infant Feeding Tube Size:8FG, length 50 cm (min.)</p> <ul style="list-style-type: none"> • 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 	Each Piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<ul style="list-style-type: none"> Radio opaque line Sterile 		
30.	S-10 (c)	Infant Feeding Tube Size:5FG length 50 cm (min.) <ul style="list-style-type: none"> 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
31.	S-11	Sterile Disposable Perfusion Set with Airway and Needle (Adult Use) <ul style="list-style-type: none"> 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
32.	S-12	Sterile Disposable Perfusion Set (Infusion set) with Airway and Needle (Paediatric Use) <ul style="list-style-type: none"> 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
33.	S-13	Sterile Disposable Infusion Set with Microdrip (I.V.) <ul style="list-style-type: none"> 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
34.	S-14	Insulin syringe (40 units) with (fixed) 30 G needle As per (phle Shall conform to tha)IS 12227	Unit	Class B
35.	S-15 (a)	Sterile Disposable (Single Use) Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock. Size 16G <ul style="list-style-type: none"> Should be packed in transparent, single blister pack. As per IS 10555 standard 	Each Piece	Class B
36.	S-15 (b)	Sterile Disposable (Single Use Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock.) Size 18G <ul style="list-style-type: none"> Should be packed in transparent, single blister pack. As per IS 10555 standard 	Each Piece	Class B
37.	S-15 (c)	Sterile Disposable (Single Use) Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock. Size 20G <ul style="list-style-type: none"> Should be packed in transparent, single blister pack. As per IS 10555 standard 	Each Piece	Class B
38.	S-15 (d)	Sterile Disposable (Single Use) Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock. Size 22G <ul style="list-style-type: none"> Should be packed in transparent, single blister pack. As per IS 10555 standard 	Each Piece	Class B
39.	S-15 (e)	Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula without port. Size 24G <ul style="list-style-type: none"> Suitable for paediatric & neonatal use Should be packed in transparent, single blister pack. As per IS 10555 standard 	Each Piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
40.	S-16	Mucus Extractor Sterile <ul style="list-style-type: none"> • Clear transparent container • Antibacterial filter • Soft, kink resistant PVC tubing • Tube Size 10 FG; Length 40 cm (min.) • Capacity 25 ml 	Unit	Class B
41.	S-17(a)	Nasal Oxygen Cannula (Set), Twin Bore (accessory for compressed air breathing) All Sizes (Adult) <ul style="list-style-type: none"> • 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
42.	S-17(b)	Nasal Oxygen Cannula (Set), Twin Bore (accessory for compressed air breathing) All Sizes (Pediatrics) <ul style="list-style-type: none"> • 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
43.	S-18	Paper Adhesive Plaster 1" X 9.0 mts (with cutter) Non woven adhesive tape, hypoallergic, should have stretch bonding	Unit	Class B
44.	S-19	Paper Adhesive Plaster 2" X 9.0 mts (with cutter) Non woven adhesive tape hypoallergic, should have stretch bonding	Unit	Class B
45.	S-20	Paper Adhesive Plaster 3" X 9.0 mts (with cutter) Non woven adhesive tape hypoallergic, should have stretch bonding	Unit	Class B
46.	S-21	Plaster of Paris Bandages 15cm X 2.7mts / Roll Testing Parameter Should Be Followed As Per BP Standard	Unit	Class B
47.	S-22	Plaster of Paris Bandages 10cm X 2.7mts / Roll Testing Parameter Should Be Followed As Per BP Standard	Unit	Class B
48.	S-23 (a)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 10 <ul style="list-style-type: none"> • 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-23 (b)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 12 <ul style="list-style-type: none"> • 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 (a)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 14 <ul style="list-style-type: none"> • 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

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<ul style="list-style-type: none"> • With luer connector / closure • Length 105 cm 		
51.	S-24 (b)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 16 <ul style="list-style-type: none"> • 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
52.	S-24 (c)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 18 <ul style="list-style-type: none"> • 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
53.	S-25(a)	Scalp Vein Set (Disposable): Size 18G <ul style="list-style-type: none"> • 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(b)	Scalp Vein Set (Disposable): Size 20G <ul style="list-style-type: none"> • 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-25(c)	Scalp Vein Set (Disposable): Size 22G <ul style="list-style-type: none"> • 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
56.	S-25(d)	Scalp Vein Set (Disposable): Size 24G <ul style="list-style-type: none"> • 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
57.	S-26	Sterile Hypodermic Syringe with Needle attached, 24G, Single Use - 2 ml <ul style="list-style-type: none"> • Clear transparent chamber • Prominent graduation • Inert material gasket at the piston to minimise friction during movement & 	Unit	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<p>prevent leakage and back flow</p> <ul style="list-style-type: none"> • 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. 		
58.	S-27	<p>Sterile Hypodermic Syringe with Needle attached, 24G, Single Use - 5 ml</p> <ul style="list-style-type: none"> • 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-28	<p>Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 10 ml</p> <ul style="list-style-type: none"> • 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
60.	S-29	<p>Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 20 ml</p> <ul style="list-style-type: none"> • 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
61.	S-30 (a)	<p>Surgical Blade Sterile, Size 11</p> <ul style="list-style-type: none"> • 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
62.	S-30 (b)	<p>Surgical Blade Sterile, Size 15</p> <ul style="list-style-type: none"> • 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
63.	S-30 (c)	<p>Surgical Blade Sterile, Size 22</p> <ul style="list-style-type: none"> • 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 	100Blades/ Packet	ND

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		surfaces of the blade shall be smooth and free from tool marks and any sign of corrosion. <ul style="list-style-type: none"> As per IS 3319 		
64.	S-31	Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 <ul style="list-style-type: none"> It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. As per IS -9165 	6 Nos. /Pkt.	ND
65.	S-32	Suture Needles Curved 1/2 Circle Round Body Assorted Size 1-5 <ul style="list-style-type: none"> It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. As per IS -9165 	6 Nos. /Pkt.	ND
66.	S-33	Suture Needles Curved 1/2 Circle Round Body Assorted Size 16-20 <ul style="list-style-type: none"> It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. As per IS -9165 	6 Nos. /Pkt.	ND
67.	S-34	Suture Needles Curved 1/2 Circle Round Body Assorted Size 6-10 <ul style="list-style-type: none"> It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. As per IS -9165 	6 Nos. /Pkt.	ND
68.	S-35	Suture Needles Curved And Cutting 1/2 Circle Cutting Size 6-10 <ul style="list-style-type: none"> It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. As per IS -9165 	6 Nos. /Pkt.	ND
69.	S-36	Suture Needles Curved And Cutting 1/2 Circle Size 11-15 <ul style="list-style-type: none"> It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. As per IS -9165 	6 Nos. /Pkt.	ND
70.	S-37	Suture Needles Curved And Cutting 1/2 Circle Size 16-20 <ul style="list-style-type: none"> It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. As per IS -9165 	6 Nos. /Pkt.	ND
71.	S-38	Suture Needles Curved And Cutting Size 1-5 <ul style="list-style-type: none"> It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. As per IS -9165 	6 Nos. /Pkt.	ND
72.	S-39(a)	Sterile Disposable Spinal Needle for Single Use 22G x 3 ½ inch <ul style="list-style-type: none"> Clear / transparent hub Sharp tip which should ensure minimal puncture trauma 	Each piece	Class B
73.	S-39(b)	Sterile Disposable Spinal Needle for Single Use 25G x 3 ½ inch <ul style="list-style-type: none"> Clear / transparent hub Sharp tip which should ensure minimal puncture trauma 	Each piece	Class B
74.	S-40	Urine Collecting Bag, Disposable 2000 ml <ul style="list-style-type: none"> 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
75.	S-41 (a)	Double J Stent, Sterile, Both Ends Open - size 4F, length 16 cm <ul style="list-style-type: none"> Radio opaque Should be of inert material, non- irritant to tissue 	Each piece	Class B
76.	S-41 (b)	Double J Stent, Sterile, Both Ends Open, size 5F, length 20 cm <ul style="list-style-type: none"> Radio opaque Should be of inert material, non- irritant to tissue 	Each piece	Class B
77.	S-42 (a)	Double J Stent, Sterile, One End Closed - size 4F, length 16 cm <ul style="list-style-type: none"> Radio opaque 	Each piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<ul style="list-style-type: none"> Should be of inert material, non- irritant to tissue 		
78.	S-42 (b)	Double J Stent, Sterile, One End Closed, size 5F, length 20 cm <ul style="list-style-type: none"> Radio opaque Should be of inert material, non- irritant to tissue 	Each piece	Class B
79.	S-43(a)	Endotracheal Tube, Plain - Size 2.5mm <ul style="list-style-type: none"> 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(b)	Endotracheal Tube, Plain - Size 3mm <ul style="list-style-type: none"> 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
81.	S-43(c)	Endotracheal Tube, Plain - Size 3.5mm <ul style="list-style-type: none"> 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-43(d)	Endotracheal Tube, Plain - Size 4mm <ul style="list-style-type: none"> 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
83.	S-43(e)	Endotracheal Tube, Plain - Size 4.5mm <ul style="list-style-type: none"> 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
84.	S-43(f)	Endotracheal Tube, Plain - Size 5mm <ul style="list-style-type: none"> 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
85.	S-43(g)	Endotracheal Tube, Plain - Size 5.5mm <ul style="list-style-type: none"> 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
86.	S-43 (h)	Endotracheal Tube, Plain with radio-opaque line, Sterile, Single Use - Size 6mm <ul style="list-style-type: none"> 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
87.	S-43(i)	Endotracheal Tube, Plain - Size 6.5mm <ul style="list-style-type: none"> Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nasal and oral intubation 	Each piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<ul style="list-style-type: none"> • Single use, sterile 		
88.	S-43(j)	Endotracheal Tube, Plain - Size 7mm <ul style="list-style-type: none"> • 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
89.	S-43(k)	Endotracheal Tube, Plain - Size 7.5mm <ul style="list-style-type: none"> • 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
90.	S-43(l)	Endotracheal Tube, Plain - Size 8mm <ul style="list-style-type: none"> • 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
91.	S-43(m)	Endotracheal Tube, Plain - Size 8.5mm <ul style="list-style-type: none"> • 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
92.	S-44(a)	Endotracheal Tube, Cuffed - Size 4mm <ul style="list-style-type: none"> • 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
93.	S-44(b)	Endotracheal Tube, Cuff - Size 4.5mm <ul style="list-style-type: none"> • 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
94.	S-44(c)	Endotracheal Tube, Cuff - Size 5mm <ul style="list-style-type: none"> • 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
95.	S-44(d)	Endotracheal Tube, Cuff - Size 6mm <ul style="list-style-type: none"> • 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

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
96.	S-44 (e)	Endotracheal Tube, Cuff - Size 6.5mm <ul style="list-style-type: none"> • 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
97.	S-44(f)	Endotracheal Tube, Cuff - Size 7mm <ul style="list-style-type: none"> • 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
98.	S-44(g)	Endotracheal Tube, Cuff - Size 7.5 <ul style="list-style-type: none"> • 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
99.	S-44(h)	Endotracheal Tube, Cuff - Size 8 <ul style="list-style-type: none"> • 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
100.	S-44(i)	Endotracheal Tube, Cuff - Size 8.5 <ul style="list-style-type: none"> • 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
101.	S-44(j)	Endotracheal Tube, Cuff - Size 9 <ul style="list-style-type: none"> • 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
102.	S-45	Tracheostomy Tube (PVC), Plain, Sterile, Single Use - All Sizes <ul style="list-style-type: none"> • 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
103.	S-46	Tracheostomy Tube (PVC), Cuffed, Sterile, Single Use - All Sizes <ul style="list-style-type: none"> • Soft flexible flange at for easy fixation • 15 mm connector at terminal end which can be rotated in 360 degree direction • Non-irritant 	Each Piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<ul style="list-style-type: none"> Radio-opaque line Balloon with non return valve 		
104.	S-47(a)	Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag (2000 ml) (size 24) <ul style="list-style-type: none"> 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
105.	S-47(b)	Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag (2000 ml) (size 28) <ul style="list-style-type: none"> 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
106.	S-47(c)	Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag (2000 ml) (size 32) <ul style="list-style-type: none"> 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
107.	S-48	Corrugated Drainage Sheet, Sterile, Multichannel, with radio opaque line, Single Use - All sizes	Each Piece	ND
108.	S-73	Polypropylene Nonabsorbable Synthetic Surgical Mesh 7.5 cmX 15 cm soft to feel fast edges,slightly stretchbonding.	Piece	Class C
109.	S-74	Polypropylene Nonabsorbable Synthetic Surgical Mesh 15 cmX 15 cm soft to feel fast edges,slightly stretchbonding.	Piece	Class C
110.	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
111.	S-80	Bone Wax Sterilised	2.5 gm/ Packet	Class C
112.	S-81	Temporary Cardiac Pacing Wire (Electrode) Sterile ½ Cir, Tapercut, 26 mm; straight cutting 60 mm ,breakaway	Sachet	ND
113.	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
114.	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
115.	S-84(b)	K Wire, length 375 mm;1.6mm <ul style="list-style-type: none"> Length of wire should be mentioned with specification. As per IS 8261 	Each Unit	Class B
116.	S-84(c)	K Wire, length 375 mm; size 1.8mm <ul style="list-style-type: none"> Length of wire should be mentioned with specification. As per IS 8261	Each Unit	Class B
117.	S-85	Face Mask, Disposable <ul style="list-style-type: none"> 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 	Piece	ND

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<ul style="list-style-type: none"> 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. 		
118.	S-86 (a)	<p>Surgical Cap, Disposable (For Surgeons)</p> <ul style="list-style-type: none"> Should be manufactured from non woven fabric. Strip for tying the cap stitched on the back for proper grip on the forehead. Green colour Ultrasonically stitched Air permeable/breathable Should retain skin and hair particle. Strip for tying the cap 	Piece	ND
119.	S-86 (b)	<p>Surgical Cap, Disposable (For Nurses)</p> <ul style="list-style-type: none"> 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
120.	S-87(a)	<p>Foldable Intra Ocular lense with injector (Size + 11 D to +17.5 D) Size:6mm optics. 12-13mm total diameter</p> <ol style="list-style-type: none"> Made of foldable Acrylic (Hydrophobic) material Bi-Convex single piece IOL with aspheric optics Size:6mm optics. 12-13mm total diameter. Modified C loop haptic/plate haptics (IOL should have UV blocking capability IOL should have 360°square edge.. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision Diopters- + 11 D to +17.5 D at 0.5 D step. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. 	Each piece	Class C
121.	S-87(b)	<p>Foldable Intra Ocular lense with injector (Size + 18 D to + 24 D) Size:6mm optics. 12-13mm total diameter</p> <ol style="list-style-type: none"> Made of foldable Acrylic (Hydrophobic) material Bi-Convex single piece IOL with aspheric optics Size:6mm optics. 12-13mm total diameter. Modified C loop haptic/plate haptics IOL should have UV blocking capability IOL should have 360°square edge.. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision Diopters- + 18 D to + 24 D at 0.5 D step. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. 	Each piece	Class C
122.	S-87(c)	<p>Foldable Intra Ocular lense with injector (Size + 24.5 D to + 28.5 D) Size:6mm optics. 12-13mm total diameter</p> <ol style="list-style-type: none"> Made of foldable Acrylic (Hydrophobic) material Bi-Convex single piece IOL with aspheric optics Size:6mm optics. 12-13mm total diameter. Modified C loop haptic/plate haptics IOL should have UV blocking capability IOL should have 360°square edge.. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision Diopters- + 24.5 D to + 28.5 D at 0.5 D step. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. 	Each piece	Class C
123.	S-	Standard PMMA Intra Ocular Lenses (Size + 11 D to +17.5 D)	Each piece)	Class C

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
	88(a)	<ul style="list-style-type: none"> • 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. 		
124.	S-88(b)	<p>Standard PMMA Intra Ocular Lenses (Size + 18 D to + 24 D)</p> <ul style="list-style-type: none"> • 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- + 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. 	Each piece	Class C
125.	S-88(c)	<p>Standard PMMA Intra Ocular Lenses (Size + 24.5 D to + 28.5 D)</p> <ul style="list-style-type: none"> 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. 	Each piece	Class C
126.	S-89(a)	<p>Disposable Sterile Surgical Rubber Gloves Size 8 Inches</p> <ul style="list-style-type: none"> • 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
127.	S-89(b)	<p>Disposable Sterile Surgical Rubber Gloves Size 8 Inches</p> <ul style="list-style-type: none"> • 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
128.	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. As per IS 15354	Dispenser Box of 100 Gloves	ND
129.	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 As per IS 15354	Dispenser Box of 100 Gloves	ND
130.	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 As per IS 15354	Dispenser Box of 100 Gloves	ND
131.	S-90 (d)	Rubber examination gloves made of natural rubber latex. Non-sterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Large As per IS 15354	Dispenser Box of 100 Gloves	ND
132.	S-91	<p>Pressure Monitoring Line / High Pressure Extension Line</p> <ul style="list-style-type: none"> • 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 	Each piece in Blister Pack	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		standard equipment. Luer lock connectors should provide secure fitting. <ul style="list-style-type: none"> • Pressure upto 800 psi • Length 200 cm • Sterile 		
133.	S-92	Urine Collecting Bag for new born / Paediatric urine collecting Bag <ul style="list-style-type: none"> • 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
134.	S-93	Umbilical Catheter (for New Born) All sizes <ul style="list-style-type: none"> • Radio opaque line • With female flexible mount • Colour coded connector • Open tip should be soft, rounded, atraumatic • Length 40 cm 	Each Piece	Class B
135.	S-94	Umbilical Cord Clamp <ul style="list-style-type: none"> • Suitable for clamping umbilical cord of new born • Security lock to prevent accidental opening after clamping • Grooved clamping area 	Each piece	Class A
136.	S-95	Absorbable Oxidized Regenerated Cellulose net size 2"x 3" Topical Absorbable Haemostatic Bactericidal Property	Each piece	Class D
137.	S-96A	Close wound Drainage Device under negative pressure (Closed Wound Suction Unit) <ul style="list-style-type: none"> • 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
138.	S-96B	Close wound Drainage Device under negative pressure (Closed Wound Suction Unit) <ul style="list-style-type: none"> • 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 18 FG 	Each Piece	Class B
139.	S-97	T – Tube for Common Bile Duct Drainage <ul style="list-style-type: none"> • Kehr's T Tube made from medical grade PVC, and siliconized • Smooth, kink resistant • Radio opaque line throughout the length • Sterile • Length 20 x 60 cm • Size 10 to 18 FG 	Each piece	ND
140.	S-98	Bone cement with antibiotics,fast and slow setting	40 GM PACK	Class C
141.	S-99	Sanitary Napkins (for Menstrual Hygiene) Specifications:- <ul style="list-style-type: none"> • 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. 		

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017												
		<ul style="list-style-type: none"> • 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. 														
	S-99(a)	<p>Sanitary Napkin, Beltless</p> <ol style="list-style-type: none"> 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) <table border="0"> <tr> <td></td> <td>Absorbent section</td> <td>Total</td> </tr> <tr> <td>Pad Length</td> <td>210 +_ 10</td> <td>230 +_ 10</td> </tr> <tr> <td>Width</td> <td>60 to 75</td> <td>70 to 85</td> </tr> <tr> <td>Thickness</td> <td>8 +_ 2</td> <td></td> </tr> </table> <ol style="list-style-type: none"> 5. Weight : Not more than 10 gm . . Instruction for usage should be mentioned on every packet <p>Instruction for usage should be mentioned on every packet</p> <p>(B). Disposable Individual Pouch/Wrapper for Each Sanitary Napkin (as per notification of Ministry of Environment, Forest and Climate Change Dated 08.04.2016)</p> <p>Pouch/Wrapper Specifications:-</p> <ol style="list-style-type: none"> 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. <p>Note:- Instruction for use of disposable pouch/wrapper must be written in Hindi on disposable pouch/wrapper -</p> <p>“इस्तेमाल किये हुये सेनेटरी नेपकिन को मोड कर Disposable Pouch/Wrapper में डाले एवं Pouch/Wrapper को गोंद लगी पट्टी से बन्द कर सुरक्षित तरीके से कूड़ेदान में डालें। ”</p>		Absorbent section	Total	Pad Length	210 +_ 10	230 +_ 10	Width	60 to 75	70 to 85	Thickness	8 +_ 2		6 napkins per pack	ND
	Absorbent section	Total														
Pad Length	210 +_ 10	230 +_ 10														
Width	60 to 75	70 to 85														
Thickness	8 +_ 2															
142.	S-99(b)	<p>Sanitary Napkin, Belttype</p> <ol style="list-style-type: none"> 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) <table border="0"> <tr> <td>Absorbent section</td> <td></td> </tr> <tr> <td>Absorbing Pad Length</td> <td>220 +_ 10(overall pad length 550+-10mm) with absorbing pad lying in the center</td> </tr> <tr> <td>Width</td> <td>70 +_ 5</td> </tr> <tr> <td>Thickness</td> <td>17 +_ 3</td> </tr> </table> <ol style="list-style-type: none"> 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 	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	6 napkins per pack	ND				
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															

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		packet.		
143.	S-99(P)	<p>Name of Item- Belt-less Sanitary Napkin with wings</p> <p>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</p> <p>2. Overall Length (mm) 230 ± 5</p> <p>3. Core length 220 mm± 10</p> <p>4. Fluff core/pad length 220 mm± 10</p> <p>5. Over all width with wings 160mm+_5</p> <p>6. Fluff core/pad length 70 mm± 5</p> <p>7. Thickness of a single pad 9-10mm</p> <p>8. Weight of a single pad : 8-10 gm</p> <p>9. Pack Six napkins in a pack.</p> <p>10 Type.- Belt-less Sanitary Napkin with wings</p> <p>11. Minimum Absorbency: 50ml</p> <p>12. pH value of absorbent material 6-8.5</p> <p>B. DISPOSABLE Individual pouch for each sanitary napkin(as per notification of ministry of environment, forest and climate change dated 08.04.2016)</p> <p>Pouch specifications:-</p> <p>1. Pouch should be of the size of sanitary napkin being supplied.</p> <p>2. It should have adhesive to seal the sanitary napkin within.</p> <p>3. Pouch should not be transparent.</p> <p>Note:-Instructions for use of disposable pouch must be written in Hindi on disposable pouch.</p> <p>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 कूड़ेदान में डालें।</p>	6napkins per pack	ND
144.	S-100	<p>Oxygen mask (Adult)</p> <ul style="list-style-type: none"> • 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
145.	S-101	<p>Oxygen mask (Paediatric)</p> <ul style="list-style-type: none"> • 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
146.	S-102	<p>Sterile Catheter, single Use, for Urinary Drainage(Foley Balloon Catheter), 2 way, Size 14</p> <ul style="list-style-type: none"> • 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 balloon capacity should be mentioned as per IS 11497 	Each piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		<ul style="list-style-type: none"> Specification for B,C,D,E,F,G should be mentioned as per IS 11497 		
147.	S-103	<ul style="list-style-type: none"> Nelaton-catherer size 14FG 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
148.	S-104	ECG Electrode <ul style="list-style-type: none"> Reliable trace, High conductivity, Easy to handle 	Each Piece	Non drug
149.	S-105	Surgical Blade Sterile, Size 23 <ul style="list-style-type: none"> 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 	Each Piece	Non drug
150.	S-106	Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 50 ml <ul style="list-style-type: none"> 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
151.	S-107	Urethral Catheter 90 (FG-14), made up of medical grade PVC	Each Piece	Class B
152.	S-108	Urethral Catheter 91 (FG-10), made up of medical grade PVC	Each Piece	Class B
153.	S-109	Vaccum Suction Set, 2.5 meter Length, <ul style="list-style-type: none"> Suction handle with Suction Tube Sterile, Pyrogenic Free, Latex free, Single use 	Each Piece	Class B
154.	S-110	Epidural Minipack 18G, 80mm – 90mm , Metal Stylet For Single Use only, <ul style="list-style-type: none"> 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
155.	S-111	Vascular Catheter with metal Guide No. 16, Double Lumen Size 30 cm (Longline IV.)	Each Piece	Class B
156.	S-112	Vascular Catheter with metal Guide No. 18 Double Lumen Size 30 cm (Longline IV.)	Each Piece	Class B
157.	S-113	Vascular Catheter with metal Guide No. 20 Double Lumen Size 30 cm (Longline IV.)	Each Piece	Class B
158.	S-114	Vascular Catheter with metal Guide No. 22 Double Lumen Size 30 cm (Longline IV.)	Each Piece	Class B
159.	S-115	Vascular Catheter with metal Guide No. 16 Double Lumen Size 45 cm (Longline IV.)	Each Piece	Class B

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
160.	S-116	Vascular Catheter with metal Guide No. 18 Double Lumen Size 45 cm (Longline IV.)	Each Piece	Class B
161.	S-117	Vascular Catheter with metal Guide No. 20 Double Lumen Size 45 cm (Longline IV.)	Each Piece	Class B
162.	S-118	Vascular Catheter with metal Guide No. 22 Double Lumen Size 45 cm (Longline IV.)	Each Piece	Class B
163.	S-119	3 Way Stop Cock , Non Pyrogenic & Single Use, should be leak proof, with smooth movements	Each Piece	Class B
164.	S-120	3 Way Stop Cock with extension Tube (Vein-O Extension line) size 10 cm (Non Pyrogenic & Single Use)	Each Piece	Class B
165.	S-121	3 Way Stop Cock with extension Tube (Vein-O Extension line) size 50 cm (Non Pyrogenic & Single Use)	Each Piece	Class B
166.	S-122	3 Way Stop Cock with extension Tube (Vein-O Extension line) size 100 cm (Non Pyrogenic & Single Use)	Each Piece	Class B
167.	S-123	3 Way Stop Cock with extension Tube (Vein-O Extension line size 150 cm (Non Pyrogenic & Single Use)	Each Piece	Class B
168.	S-124	Abdominal Drain Kit, Sterile, having drainage catheter and Collection Bag (2000 ml) (size 16) <ul style="list-style-type: none"> • 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
169.	S-125	Abdominal Drain Kit, Sterile, having drainage catheter and Collection Bag (2000 ml) (size 20) <ul style="list-style-type: none"> • 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
170.	S-126	Nasal Pronge Neonatal (Flexible Medical Grade, 2 Meter Long, Multichannel Kink Resistance Tube	Each Piece	Class B
171.	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
172.	S-128	Sterile Disposable (Single Use Teflon/PTFE I.V Cannula with integrated 3 way stop cock Size 26G <ul style="list-style-type: none"> · Should be packed in transparent single blister pack · Should confirm to IS 10555 standard · (Neonatal IV Cannula Size 26) 	Each Piece	Class B
173.	S-129	NIV Mask (Noninvasive Ventilation Mask) Adult <ul style="list-style-type: none"> · Should be light weight Oro nasal covering (nose & mouth) mask with face & forehead soft cushion pads 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 	Each Piece	Non Drug
174.	S-130	NIV Mask (Noninvasive Ventilation Mask) Adult <ul style="list-style-type: none"> · Should be light weight Oro nasal covering (nose & mouth) mask with face & forehead soft cushion pads for adults in Medium size. · Should be with ergonomically designed clips/straps for easy disengagement 	Each Piece	Non Drug

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
		of the head gear. · Should be Single Use for Ventilator without vent · Non allergic, leak proof, contour should be maintained		
175.	S-131	NIV Mask (Noninvasive Ventilation Mask) Adult · Should be light weight Oro nasal covering (nose & mouth) mask with face & forehead soft cushion pads 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	Each Piece	Non Drug
176.	S-132	NIV Mask (Noninvasive Ventilation Mask) Adult · Should be light weight Oro nasal covering (nose & mouth) mask with face & forehead soft cushion pads 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	Each Piece	Non Drug
177.	S-133	NIV Mask (Noninvasive Ventilation Mask) Paediatric <ul style="list-style-type: none"> • Should be light weight oro nasal mask with soft cushion pads in small size • Should be with ergonomically designed clips/straps for easy 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 	Each Piece	Non Drug
178.	S-134	Nebulization Mask Adult	Each Piece	Non Drug
179.	S-135	Nebulization Mask Paediatric	Each Piece	Non Drug
180.	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
181.	S-137	Chemotherapy Port & Non-coring needles (Paediatric) · 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
182.	NE32 A	Specifications of Bed side Leucodepletion Filters for Blood Transfusion:-(For one unit of red cell) <ol style="list-style-type: none"> 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. 	40 Filters per Box	-

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Class As per Medical Device Rules 2017
183.	NE32 B	<p>Specifications of Bed side Leucodepletion Filters for Blood Transfusion:-(For two unit of red cell)</p> <ol style="list-style-type: none"> 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 0.5×10^5 residual leucocytes for one unit of red cell and 0.2×10^6 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 $\geq 40 \mu\text{m}$, micro aggregate filter. 9. Should be US FDA/ European CE Certified. 	40 Filters per Box	-

ANNEXURE VIII

Clause 2(8)

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

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
1	2	3	4		5	6
1	S-1	Absorbable Gelatin Sponge IP 66, Size 80 +- 10 mm x 50 mm x 10 mm . Should be sterlised	Piece	A	Physical	
				1	Description	
				B	Chemical	
				1	Water Absorbance	
				2	Density	
				3	Formaldehyde	
				4	Total Nitrogen	
				5	Digestibility	
				6	Solubility	
				7	Porosity	
				8	Ash	
				9	Water	
				C	Biological Test	
				1	Sterility	
2	Pyrogen / Bacterial Endotoxins Test					
2	S-2	Absorbent Cotton Wool IP 500 gm	Packet	A	Physical	
				1	Description	
				2	Colouring Matter	
				B	Chemical test	
				1	Identification A By Microscopic	
				2	Identification B By Chemically	
				3	Identification C By Chemically	
				4	Acidity or Alkalinity	
				5	Surface active substance	
				6	Absorbency	
				a	Absorbency A Sinking Time	
				b	Absorbency B Water holding capacity	
				7	Foreign fibres	
				8	Fluorescence	
9	Ether Soluble Substances					
10	Water Soluble Substances					
11	Neps					
12	Sulphated Ash					
13	Loss On Drying					
3	S-3	Asepto Syringe with	Piece	A	Physical	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
		Transparent Bulb, Sterile, 60 ml		1	Description	
				2	Components	
				3	Freedom from extraneous Matter	
				4	Leakage	
				5	Capacity	
				6	Transparency	
				B	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
4	S-4	Blood Administration Set / Blood Transfusion Set Conforms to IS 9824-3:1996	Unit	A	Physical	
				1	Tubing (Length, Internal Diameter., other properties- kink resistance, transparency)	
				2	Closure -Piercing Device	
				3	Connection between male fitting, injection site and tubing	
				4	Air - inlet device	
				5	Filter	
				6	Drip chamber and drip tube	
				7	Filter for Blood and Blood derivatives	
				8	Flow Regulator	
				9	Test for injection Site	
				10	Test for Integrity	
				11	Tensile Strength	
				12	Particulate Contamination	
				13	Protective Cap	
				14	Blood Flow Rate	
				15	Male Fitting	
				16	Test for filter efficiency	
				B	Chemical test	
				1	Reducing (Oxidizable) Matter	
				2	Heavy Metal Ions	
				3	Acidity or Alkalinity	
				4	Residue on evaporation	
				5	UV Absorbance	
				C	Biological Test	
				1	Sterility Test	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity Test	
				D	For Needles	
				1	Description	
				2	Cleanliness	
				3	Limits of Acidity or Alkalinity	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				4	Limits of Extractable Matels	
				5	Freedm from defects	
				6	Tolerance of length	
				7	Lubricant	
				8	Needle Point	
5	S-5(a,b)	Disposable Sterile Surgical Rubber Gloves, Size 6 ½ Inches IS 13422	Pair	A	Physical	
				1	Dimension (Length, width)	
				2	Thickness	
				3	Cuff	
				4	Finger	
				5	Palm	
				6	Tensile Strength (Mpa) (Before Ageing)	
				7	Tensile Strength (Mpa) (After Ageing)	
				8	Elongation at break (%) (Before Ageing)	
				9	Elongation at break (%) (After Ageing)	
				10	Stress at 500% (Mpa) (Before Ageing)	
				11	Air Tight Test	
				B	Biological Test	
				1	Sterility	
6	S-6(a,b)	Disposable Sterile Surgical Rubber Gloves Size 7 Inches IS 13422	Pair	A	Physical	
				1	Dimension (Length, width)	
				2	Thickness	
				3	Cuff	
				4	Finger	
				5	Palm	
				6	Tensile Strength (Mpa) (Before Ageing)	
				7	Tensile Strength (Mpa) (After Ageing)	
				8	Elongation at break (%) (Before Ageing)	
				9	Elongation at break (%) (After Ageing)	
				10	Stress at 500% (Mpa) (Before Ageing)	
				11	Air Tight Test	
				B	Biological Test	
				1	Sterility	
7	S-7(a,b)	Disposable Sterile Surgical Rubber Gloves Size 7½ Inches IS 13422	Pair	A	Physical	
				1	Dimension (Length, width)	
				2	Thickness	
				3	Cuff	
				4	Finger	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				5	Palm	
				6	Tensile Strength (Mpa) (Before Ageing)	
				7	Tensile Strength (Mpa) (After Ageing)	
				8	Elongation at break (%) (Before Ageing)	
				9	Elongation at break (%) (After Ageing)	
				10	Stress at 500% (Mpa) (Before Ageing)	
				11	Air Tight Test	
				B	Biological Test	
				1	Sterility	
8	S-8 (a), (b), (c), (d), (e), (f), (g), (h), (i), (j)	Suction Catheter, Sterile: FG 5,6,8,10,12,14,16,18,20,22 ISO 8836:2014	Each Piece	A	Physical	
				1	Description	
				2	Shape and dimensions	
				3	Length	
				4	Funnel Connector	
				5	Diameter of Tube	
				6	Joint Strength / Security of construction	
				7	Leakage of test	
				8	Tip	
				9	No. of efes	
				10	Elongation Test	
				11	Residual Vacuum	
				B	Biological Test	
				1	Sterility	
9	S-9 (a), (b), (c), (d), (e), (f), (g)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size 8 FG, 10FG, 16FG, 18FG, 20FG, 22FG, 24FG IS 11497	Each Piece	A	Physical	
				1	Description	
				2	Shape and dimensions	
				3	Wall of Thickness	
				4	Length of catheter	
				5	Valve	
				6	Ballon Capacity	
				7	Diameter of Catheter	
				8	Tensile strength of rubber	
				9	Elongation at Break	
				10	PH	
				11	Balloon Leakage	
				12	Workmanship and surface finish	
				B	Chemical test	
				1	pH of water extract	
				2	Extractable Colour	
				3	Heavy metals	
				C	Biological Test	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				1	Sterility	
10	S-10 (a), (b), (c),	Infant Feeding Tube Size 10FG, 8FG, 5FG, Length 50cm		A	Physical	
				1	Description	
				2	Tip	
				3	No. of efes	
				4	Length	
				5	Strength of Joints	
				6	Radio opaque line	
				7	Particulate Matter	
				8	Components	
				9	Leakage	
				B	Biological Test	
				1	Sterility	
				2	Toxicity	
3	Pyrogen / Bacterial Endotoxins Test					
11	S-11	Sterile Disposable Perfusion Set with Airway and Needle (Adult Use) IS 12655- 4	Unit	A	Physical	
				1	Description	
				2	Tubing (Length, other properties- flexibility, transparency)	
				3	Test of Integrity	
				4	Connection between components	
				5	Closure piercing device	
				6	Drip chamber and drip tube	
				7	Air inlet device	
				8	Flow Rate	
				9	Flow Regulator	
				10	Latex Bulb	
				11	Male Fitting	
				12	Test for efficiency of fluid filter	
				13	Test of Injection site	
				14	Particulate contamination	
				15	Protective Cap	
				B	Chemical test	
				1	Acidity or Alkalinity	
				2	UV absorption of extract	
				3	Reducing (Oxidizable) Substance	
				4	Metal ions	
				5	Non Volatile Residue	
				C	Biological Test	
				1	Sterility Test	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Haemolysis	
				4	Toxicity Test	
12	S-12	Sterile Disposable	Unit	A	Physical	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder		
		Perfusion Set (Infusion set) with Airway and Needle (Paediatric Use) (with Burette type measured volume chamber) ISO 8536-5		1	Description			
				2	Test of Integrity			
				3	Connection between components			
				4	Closure piercing device			
				5	Tubing (Length, other properties-flexibility, transparency)			
				6	Protective Cap			
				7	Drip chamber and drip tube			
				8	Leakage Test			
				9	Flow Rate			
				10	Flow Regulator			
				11	Injection Site			
				12	Male Fitting			
				13	Air inlet device			
				14	Burette (capacity, transparency, graduations, etc.)			
				15	Floating valve (shut off valve) function			
				16	Test for efficiency of fluid filter			
				17	Test of Injection site			
				18	Particulate contamination			
				B	Chemical test			
				1	Acidity or Alkalinity			
				2	Conductivity of extract			
				3	Reducing (Oxidizable) Substance			
				4	Metal ions			
				5	Non Volatile Residue			
				C	Biological Test			
				1	Sterility Test			
				2	Pyrogen / Bacterial Endotoxins Test			
				3	Toxicity Test			
13	S-13			Sterile Disposable Infusion Set with Microdip (I.V) IS 12655-4	Unit	A	Physical	
						1	Description	
						2	Tubing	
						3	Test of Integrity	
						4	Connection between components	
		5	Closure piercing device					
		6	Drip chamber and drip tube					
		7	Flow Rate					
		8	Flow Regulator					
		9	Injection site					
		10	Male Fitting					
		11	Test for efficiency of fluid filter					
		12	Protective Cap					
		13	Test of Injection site					

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				14	Particulate contamination	
				B	Chemical test	
				1	Acidity or Alkalinity	
				2	UV Absorbency of extract	
				3	Reducing (Oxidizable) Substance	
				4	Heavy Metal Ions	
				5	Residue on evaporation	
				C	Biological Test	
				1	Sterility Test	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity Test	
14	S-14	Insulin syringe (40 units) with (fixed) 30 G needle IS 12227	Unit	A	Physical	
				1	Description	
				2	Dimensions	
				3	Components	
				4	Freedom from extraneous Matter	
				5	Tolerance on graduated Capacity	
				6	Properties of needle	
				7	Fit of piston in barrel (Test for force required to operate plunger)	
				8	Dead space	
				9	Needle Point	
				10	Barrel	
				11	Piston/Plunger Assembly	
				12	Conical Fitting	
				13	Lubrication	
				14	Leakage at needle	
				15	Leakage past piston	
				16	Markings and Graduations Scale	
				B	Chemical Test	
				1	Limit for Extractable Metals	
				2	Limit for Acidity or Alkalinity (pH)	
				C	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
15	S-15 (a), (b), (c), (d), (e)	Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula with integrated 3 Way stop cock. Size 16G, 18G, 20G, 22G IS 10555 And Sterile Disposable (Single Use) Teflon/PTFE IV Cannula without port 24G IS 10555	Each Piece	A	Physical	
				1	Description	
				2	Dimensions (outside diameter, effective length)	
				3	Surface (free from extraneous matter)	
				4	Integrity	
				5	Force at Break	
				6	Freedom from liquid leakage under pressure	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				7	Freedom from air leakage into hub assembly	
				8	Needle and fittings	
				9	Flow rate	
				10	Needle properties (material, design, needle point, needle hub, strength of union between hub and needle tube)	
				11	Vent fitting (Test for liquid leakage from vent fitting)	
				B	Chemical Test	
				1	Acidity or Alkalinity	
				2	Corrosion Resistance	
				C	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
16	S-16	Mucus Extractor, Sterile	Unit	A	Physical	
				1	Description	
				2	Components	
				3	Particulate Matter	
				4	Tube length	
				5	Container capacity	
				6	Leakage	
				B	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
17	S-17 (a), (b)	Nasal Oxygen Cannula (Set), Twin Bore (accessory for compressed air breathing) All Sizes (Adult & Paediatric)	Each Piece	A	Physical	
				1	Description	
				2	Components	
				3	Particulate Matter	
				4	Tube Length	
				5	Kinking of Tube	
				6	Connector	
				7	Multi channel tube properties	
				8	Twin Bores	
				9	Integrity	
				10	Leakage	
				B	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
18	S-18	Paper Adhesive Plaster 1" X 9.0 mts (with cutter) Non woven adhesive tape	Unit	A	Physical	
				1	Description	
				2	Dimension (Length, width)	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				3	Tensile strength	
				4	Adhesive strength	
19	S-19	Paper Adhesive Plaster 2" X 9.0 mts (with cutter) Non woven adhesive tape	Unit	A	Physical	
				1	Description	
				2	Dimension (Length, width)	
				3	Tensile strength	
				4	Adhesive strength	
20	S-20	Paper Adhesive Plaster 3" X 9.0 mts (with cutter) Non woven adhesive tape	Unit	A	Physical	
				1	Description	
				2	Dimension (Length, width)	
				3	Tensile strength	
				4	Adhesive strength	
21	S-21	Plaster of Paris Bandages 15cm X 2.7mts / Roll	Unit	A	Physical	
				1	Description	
				2	Weight per unit area of Bandage & fabric	
				B	Chemical Test	
				1	Fiber Identification	
				2	Identification A (Cotton)	
				3	Identification B (Iodinated Zinc Chloride Solution Test)	
				4	Identification C (Solubility in Sulphuric Acid)	
				5	Identification D (Zinc Chloride Solution Test)	
				6	Threads per unit area (warp, weft)	
				7	Setting time	
				8	Content of Calcium sulphate hemihydrate	
22	S-22	Plaster of Paris Bandages 10cm X 2.7mts / Roll	Unit	A	Physical	
				1	Description	
				2	Weight per unit area of Bandage & fabric	
				B	Chemical Test	
				1	Fiber Identification	
				2	Identification A (Cotton)	
				3	Identification B (Iodinated Zinc Chloride Solution Test)	
				4	Identification C (Solubility in Sulphuric Acid)	
				5	Identification D (Zinc Chloride Solution Test)	
				6	Threads per unit area (warp, weft)	
				7	Setting time	
				8	Content of calcium sulphate Hemihydrate	
23	S-23 (a), (b)	Ryle's Tube / Nasogastric Tube Size: 10,12	Each Piece	A	Physical	
				1	Description	
				2	Components	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				3	Radio opaque line	
				4	Strength of Joints	
				5	Heavy Metal Ions	
				6	Non Volatile Residue	
				7	Residue on ignition	
				8	Buffering capacity	
				9	Markings	
				10	Funnel luer connector/closure	
				11	Length	
				12	Particulate Matter	
				13	Leakage	
				B	Biological Test	
				1	Sterility	
				2	Toxicity	
				3	Pyrogen / Bacterial Endotoxins Test	
24	S-24 (a), (b), (c)	Ryle's Tube / Nasogastric Tube Size: 14,16,18	Each Piece	A	Physical	
				1	Description	
				2	Components	
				3	Cleanliness	
				4	Material and transparency	
				5	Distal End	
				6	Proximal end	
				7	Flexibility and Smoothness	
				8	Radio opaque line	
				9	Markings	
				10	Funnel luer connector/closure	
				11	Length	
				12	Particulate Matter	
				13	Leakage	
				B	Biological Test	
				1	Sterility	
				2	Toxicity	
				3	Pyrogen / Bacterial Endotoxins Test	
25	S-25 (a), (b), (c), (d)	Scalp Vein Set (Disposable): Size 18G, 20G, 22G,24G		A	Physical	
				1	Description	
				2	Cleanliness	
				3	Adapter	
				4	Wing	
				5	Sheath	
				6	Needle length	
				7	Needle Point	
				8	Leakage Test	
				9	Block Test	
				10	Flow rate	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				11	Performance	
				12	a. Bond between wing and needle tube	
				13	b. Bond between wing and extension tube	
				14	c. Bond between extension tube & adapter	
				B	Chemical	
				1	Acidity or Alkalinity	
				2	Extractable metals	
				C	Biooical Test	
				1	Sterility	
				2	Toxicity	
				3	Pyrogen / Bacterial Endotoxins Test	
26	S-26	Sterile Hypodermic Syringe with Needle attached, 24G , Single 2ml IS 10258	Unit	A	Physical	
				1	Description	
				2	Components	
				3	Cleanliness	
				4	Lubrication	
				5	Tolerance on graduated Capacity	
				6	Graduated Scale	
				a	Overall length of scale to nominal capacity mark	
				b	Scale Interval	
				c	Increment between Graduation lines to be numbered	
				7	Barrel	
				a	Dimension	
				b	Fingergrip	
				8	Pistan/plunger Assembly	
				a	Fit of Piston in barrel	
				b	Fiducial line	
				9	Leakage Test	
				a	Liquid leakage past the syringe piston and at the syringe needle union during compression	
				b	Air leakage past the syringe piston and at the syringe needle union during aspiration	
				10	Test for Needle assembly	
				a	Needle Attachment	
				b	Needle dimensions	
				11	Bond between hub/ syringe barrel and needle tube	
				12	Patency of lumen	
				13	Dead space	
				B	Chemical test	
				1	Acidity or Alkalinity (pH)	
				2	Extractable Metals	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				C	Biological test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
27	S-27	Sterile Hypodermic Syringe with Needle attached, 24G Single Use - 5 ml IS 12050	Unit	A	Physical	
				1	Description	
				2	Components	
				3	Cleanliness	
				4	Lubrication	
				5	Tolerance on graduated Capacity	
				6	Graduated Scale	
				a	Overall length of scale to nominal capacity mark	
				b	Scale Interval	
				c	Increment between Graduation lines to be numbered	
				7	Barrel	
				a	Dimension	
				b	Fingergrip	
				8	Pistan/plunger Assembly	
				a	Fit of Piston in barrel	
				b	Fiducial line	
				9	Leakage Test	
				a	Liquid leakage past the syringe piston and at the syringe needle union during compression	
				b	Air leakage past the syringe piston and at the syringe needle union during aspiration	
				10	Test for Needle assembly	
				a	Needle Attachment	
				b	Needle dimensions	
				11	Bond between hub/ syringe barrel and needle tube	
				12	Patency of lumen	
				13	Dead space	
				B	Chemical test	
				1	Acidity or Alkalinity (pH)	
				2	Extractable Metals	
				C	Biological test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
28	S-28	Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 10 ml IS 12050	Unit	A	Physical	
				1	Description	
				2	Components	
				3	Cleanliness	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				4	Lubrication	
				5	Tolerance on graduated Capacity	
				6	Graduated Scale	
				a	Overall length of scale to nominal capacity mark	
				b	Scale Interval	
				c	Increment between Graduation lines to be numbered	
				7	Barrel	
				a	Dimension	
				b	Fingergrip	
				8	Pistan/plunger Assembly	
				a	Fit of Piston in barrel	
				b	Fiducial line	
				9	Leakage Test	
				a	Liquid leakage past the syringe piston and at the syringe needle union during compression	
				b	Air leakage past the syringe piston and at the syringe needle union during aspiration	
				10	Test for Needle assembly	
				a	Needle Attachment	
				b	Needle dimensions	
				11	Bond between hub/ syringe barrel and needle tube	
				12	Patency of lumen	
				13	Dead space	
				B	Chemical test	
				1	Acidity or Alkalinity (pH)	
				2	Extractable Metals	
				C	Biological test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
29	S-29	Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 20 ml IS 12050	Unit	A	Physical	
				1	Description	
				2	Components	
				3	Cleanliness	
				4	Lubrication	
				5	Tolerance on graduated Capacity	
				6	Graduated Scale	
				a	Overall length of scale to nominal capacity mark	
				b	Scale Interval	
				c	Increment between Graduation lines to be numbered	
				7	Barrel	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				a	Dimension	
				b	Fingergrip	
				8	Pistan/plunger Assembly	
				a	Fit of Piston in barrel	
				b	Fiducial line	
				9	Leakage Test	
				a	Liquid leakage past the syringe piston and at the syringe needle union during compression	
				b	Air leakage past the syringe piston and at the syringe needle union during aspiration	
				10	Test for Needle assembly	
				a	Needle Attachment	
				b	Needle dimensions	
				11	Bond between hub/ syringe barrel and needle tube	
				12	Patency of lumen	
				13	Dead space	
				B	Chemical test	
				1	Acidity or Alkalinity (pH)	
				2	Extractable Metals	
				C	Biological test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
30	S-30 (a), (b), (c)	Surgical Blade, Sterile Size: 11,15,22 IS:3319	100 blades / Pkt	A	Physical	
				1	Shape and Dimensions	
				2	Thickness	
				3	Hardness test	
				4	Visual Examination (particularly for nicks)	
				5	Performance Test	
				B	Biological Test	
				1	Sterility	
31	S-31	Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 Should conform to IS-9165	6 Nos. /Pkt.	A	Physical	
				1	Size, Shape and dimensions	
				2	Hardness test	
				3	Free from surface defects (Feather edges, burrs, nicks)	
				4	Flexibility	
				5	Sharpness	
				B	Chemical Test	
				1	Corrosion Resistance test	
				2	Bend Test	
32	S-32	Suture Needles Curved 1/2 Circle Round Body	6 Nos. /Pkt.	A	Physical	
				1	Size, Shape and dimensions	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
		Assorted Size 1-5 Should conform to IS-9165		2	Hardness test	
				3	Free from surface defects (Feather edges, burrs, nicks)	
				4	Flexibility	
				5	Sharpness	
				B	Chemical Test	
				1	Corrosion Resistance test	
				2	Bend Test	
33	S-33	Suture Needles Curved 1/2 Circle Round Body Assorted Size 16-20 Should conform to IS-9165	6 Nos. /Pkt.	A	Physical	
				1	Size, Shape and dimensions	
				2	Hardness test	
				3	Free from surface defects (Feather edges, burrs, nicks)	
				4	Flexibility	
				5	Sharpness	
				B	Chemical Test	
				1	Corrosion Resistance test	
		2	Bend Test			
34	S-34	Suture Needles Curved 1/2 Circle Round Body Assorted Size 6-10 Should conform to IS-9165	6 Nos. /Pkt.	A	Physical	
				1	Size, Shape and dimensions	
				2	Hardness test	
				3	Free from surface defects (Feather edges, burrs, nicks)	
				4	Flexibility	
				5	Sharpness	
				B	Chemical Test	
				1	Corrosion Resistance test	
		2	Bend Test			
35	S-35	Suture Needles Curved And Cutting 1/2 Circle Cutting Size 6-10 Should conform to IS-9165	6 Nos. / Pkt.	A	Physical	
				1	Size, Shape and dimensions	
				2	Hardness test	
				3	Free from surface defects (Feather edges, burrs, nicks)	
				4	Flexibility	
				5	Sharpness	
				B	Chemical Test	
				1	Corrosion Resistance test	
		2	Bend Test			
36	S-36	Suture Needles Curved And Cutting 1/2 Circle Size 11-15	6 Nos. / Pkt.	A	Physical	
				1	Size, Shape and dimensions	
				2	Hardness test	
				3	Free from surface defects (Feather edges, burrs, nicks)	
				4	Flexibility	
				5	Sharpness	
		B	Chemical Test			

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				1	Corrosion Resistance test	
				2	Bend Test	
37	S-37	Suture Needles Curved And Cutting 1/2 Circle Size 16-20	6 Nos. /Pkt.	A	Physical	
				1	Size, Shape and dimensions	
				2	Hardness test	
				3	Free from surface defects (Feather edges, burrs, nicks)	
				4	Flexibility	
				5	Sharpness	
				B	Chemical Test	
				1	Corrosion Resistance test	
				2	Bend Test	
38	S-38	Suture Needles Curved And Cutting Size 1-5 Should conform to IS-9165	6 Nos. / Pkt	A	Physical	
				1	Size, Shape and dimensions	
				2	Hardness test	
				3	Free from surface defects (Feather edges, burrs, nicks)	
				4	Flexibility	
				5	Sharpness	
				B	Chemical Test	
				1	Corrosion Resistance test	
				2	Bend Test	
39	S-39 (a), (b)	Sterile Disposable Spinal Needle for Single Use 22G x 3 1/2 inch & 25G x 3 1/2 inch IS:7350	Each Piece	A	Physical	
				1	Description	
				2	Dimensions	
				3	Needle Hub	
				4	Tensile strength between Styled and styled hub	
				5	Effective length of needle	
				6	Cleanliness	
				7	Leakage Test	
				8	Sharpness of Needle point	
				9	Elasticity	
				10	Reverse Bend Test	
				11	Stiffness	
				12	Security of Swaging	
				13	Freedom from Foreign Matter	
				14	Acidity or Alkalinity of needle and stylet wire	
				B	Chemical Test	
				1	Corrosion Resistance	
				C	Biological Test	
				1	Sterility	
				2	Toxicity	
				3	Pyrogen / Bacterial Endotoxins Test	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
40	S-40	Urine Collecting Bag, Disposable, 2000 ml	Unit	A	Physical	
				1	Description	
				2	Components	
				3	Capacity of graduation	
				4	Non-return valve	
				5	Inlet connector	
				6	Drainage tap	
				7	Leakage	
				B	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
				41	S-41 (a), (b)	Double J Stent, Sterile, Both Ends Open, size 4F & 5F, length 16 / 20 cm
1	Length of Stent					
2	O.D. Of Stent					
3	I.D. Of Stent					
4	Length of pusher					
5	OD of guidewire					
6	Visual Test					
7	Surface of stent					
8	Quality of J Stent tip					
9	Quality of Pusher					
10	Position of X-ray Line					
11	Performance test: Movement of guidewire in J stent					
B	Biological Test					
1	Sterility					
2	Pyrogen / Bacterial Endotoxins Test					
3	Toxicity					
42	S-42 (a), (b)	Double J Stent, Sterile, One End Closed, size 4F & 5F, length 16 / 20 cm	Each Piece	A	Physical	
				1	Length of Stent	
				2	O.D. Of Stent	
				3	I.D. Of Stent	
				4	Length of pusher	
				5	OD of guidewire	
				6	Visual Test	
				7	Surface of stent	
				8	Quality of J Stent tip	
				9	Quality of Pusher	
				10	Position of X-ray Line	
				11	Performance test: Movement of guidewire in J stent	
				B	Biological Test	
				1	Sterility	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
43	S-43 (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m)	Endotracheal Tube, Size: 2.5, 3, 3.5, 4,4.5,5,5.5, 6,6.5,7,7.5,8,8.5,		A	Physical	
				1	Description	
				2	Dimensions	
				a	Inside Diameter	
				b	Outside Diameter	
				c	Curvature	
				d	Bevel	
				e	Length	
				3	Design Features and Finish	
				4	Radio opaque line	
				5	Heavy matels	
				6	Non Volatile Residue	
				7	Residue on ignition	
				8	leakage	
				B	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
44	S-44 (a), (b), (c), (d), (e), (f), (g), (h), (i), (j)	Endotracheal Tube, Cuffed – Size:4,4.5,5,6,6.5,7,7.5,8, 8.5,9		A.	Physical	
				1	Description	
				2	Dimensions	
				a	Inside Diameter	
				b	Outside Diameter	
				c	Curvature	
				d	Bevel	
				e	Length	
				3	Cuff	
				a	Inflating of cuff	
				b	Cuff resting diameter	
				c	Tube Collapse test	
				d	Cuff herniation test	
				4	Radio opaque line	
				5	Heavy matels	
				6	Residue on ignition	
				7	Design Features and Finish	
				B	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
45	S-45	Tracheostomy Tube (PVC), Plain, Sterile,	Each Piece	A	Physical	
					Tip	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
		Single Use - All Sizes		1	Dimensions	
				a	Nominal Length	
				b	O.D. of Tube	
				c	I.D. of Tube	
				d	Angle	
				2	Radio opaque line	
				3	Blockage	
				4	Design Features and Finish	
				a	Conical Connector	
				b	Neck-Plate	
				5	Test for attachment of connector & neck plate to the tube	
				6	Packaging	
				B	Biological Test	
				1	Sterility Test	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
46	S-46			Tracheostomy Tube (PVC), Cuffed, Sterile, Single Use - All Sizes	Each Piece	A
		1	Dimensions			
		a	Nominal Length			
		b	O.D. of Tube			
		c	I.D. of Tube			
		d	Angle			
		2	Design Features			
		a	Conical Connector			
		b	Neck-Plate			
		c	Cuff			
		d	Inflating tube for cuff			
		3	Radio opaque line			
		4	Blockage			
		5	Balloon			
		6	Valve			
		7	Test for attachment of connector & neck plate to the tube			
		8	Resting diameter of cuff			
		9	Design finish			
		10	Packaging			
		B	Biological Test			
		1	Sterility Test			
		2	Pyrogen / Bacterial Endotoxins Test			
		3	Toxicity			
47	S-47 (a), (b), (c)	Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag (2000 ml) Size 24,	Each Piece	A	Physical	
				1	Description	
				2	Transparency	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
		28, 32		3	Kink resistant and flexible tube	
				4	Length	
				5	Width	
				6	O.D of catheter	
				7	O.D. of Tube	
				8	Total length of tubing	
				9	Radio opaque line	
				10	Components	
				11	Non-return valve	
				12	Graduation	
				13	Capacity	
				14	Leakage of Bag	
				15	Rounded open distal end with smooth atraumatic eyes in catheter catheter with marking at 2cm in interval	
				B	Biological Test	
				1	Sterility Test	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
48	S-48	Corrugated Drainage Sheet, Sterile, Multichannel, with radio opaque line, Single Use - All sizes	Each Piece	A	Physical	
				1	Description	
				2	Surface Finish	
				3	Length of Sheet	
				4	Width of sheet	
				5	Thickness of Sheet	
				6	Radio opaque line	
				7	Multichannel	
				8	Performance	
				B	Biological Test	
				1	Sterility Test	
49	S-73	Polypropylene Nonabsorbable Synthetic Surgical Mesh 7.5 cm X 15 cm	Piece	A	Physical	
				1	Dimensions	
				2	Surface Weight	
				3	Length	
				4	Width	
				5	Thickness	
				6	Straight pull tensile strength lengthwise	
				7	Straight pull tensile strength crosswise	
				8	Elongation lengthwise	
				9	Elongation crosswise	
				B	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
50	S-74	Polypropylene Nonabsorbable Synthetic Surgical Mesh 15 cm X 15 cm	Piece	A	Physical	
				1	Dimensions	
				2	Mash Size	
				3	Thickness	
				4	GSM	
				5	Pore Size	
				6	Brusting Strength	
				7	Suface Weight	
				8	Straight pull tensile strength lengthwise	
				9	Straight pull tensile strength crosswise	
				10	Elongation lengthwise	
				11	Elongation crosswise	
				B	Biological Test	
				1	Sterility	
2	Pyrogen / Bacterial Endotoxins Test					
51	S-79	Sterilised Umbilical Cotton Tape Width 3 mm, Length 75 cm	Each Piece	A	Physical	
				1	Colour	
				2	Length	
				3	Width	
				4	Tensile Strength	
				B	Biological Test	
				1	Sterility Test	
52	S-80	Bone Wax, Sterilised	2gm / Pkt	A	Physical	
				1	Average Weight	
				2	Weight Variation	
				B	Chemical Test	
				1	Acid Value	
				2	Saponification	
				C	Biological Test	
				1	Sterility	
53	S-81	Temporary Cardiac Pacing Wire (Electrode) Sterile ½ Cir, Tapercut, 26 mm; Straight cutting 60mm, breakaway	Sachet	A	Physical	
				1	Description	
				2	Visual Testing	
				3	Resistance	
				4	Strand Length	
				5	Diameter	
				6	Needle Testing	
				7	Tensile Testing	
				B	Biological Test	
				1	Sterility	
54	S-82	Skin Graft Knife Blade (Sterile, disposable); and Handle (Watson modification of Humby's	One Pack each	A	Physical	
				1	Shape and Dimensions	
				2	Blade hardness	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
		Knife)		3	Length	
				4	Width	
				5	Hole Length	
				6	Material	
				7	Finishing	
				8	Performance test	
				9	The entire length of the cutting edge and small angle	
				10	Straight and the center	
				11	Cutting edge shall be perfectly Straight	
				12	Blade shall be slightly polished and free from blemishes	
				B	Chemical Test	
				1	Corrosion Resistance	
				C	Biological Test	
				1	Sterility	
55	S-84 (a), (b), (c)			K Wire, length 375 mm; 1 mm, 1.6mm, 1.8mm IS - 8261	Each unit	A
		1	Ends			
		2	Diameter			
		3	Length			
		4	Tensile Strength			
		B	Chemical Test			
		1	Corrosion Resistance Test			
56	S-85	Face Mask, Disposable	Piece	A	Physical	
				1	Fabric	
				2	No. of ply / construction	
				3	High Bacterial Filtration Efficiency	
				4	Sealing of layers	
				5	Size	
				a	Length	
				b	Width	
				6	Colour	
				7	Nose Clip	
				8	Elastic Band	
				9	Droplet Test	
				10	GSM	
				a	Inner Layer	
				b	Middle Layer	
		c	Outer layer			
		11	Length of Strings			
57	S-86 (a), (b)	Surgical Cap, Disposable	Piece	A	Physical	
				1	Fabric	
				2	No. of ply / construction	
				3	Sealing of layers	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				4	Size	
				5	Colour	
				6	Thickness	
				7	Strength of Joints	
				8	Irritation of Skin	
				9	Weight of Cap	
				10	Air Permeable	
				11	Height	
				12	Length of Strings	
58	S-87 (a), (b), (c)	Foldable Intra Ocular lense with injector	Each Piece	A	Physical	
				1	Description	
				2	Mechanical Tests (Compression force, Axial displacement in compression, Optic decentration, Optic tilt, Angle of contact, Compression force decay, Dynamic fatigue durability, Loop pull strength, Surface and Bulk homogeneity)	
				3	Optical Tests	
				4	Dioptric power	
				5	Resolution Efficiency Test	
				6	MTF(modulation transfer function) test	
				B	Chemical	
				1	ETO Residual Test	
				C	Biological	
				1	Sterility test	
				2	Bacterial Endotoxins Test	
				59	S-88 (a), (b), (c)	Standard PMMA Intra Ocular Lenses
1	Description					
2	Mechanical tests (Compression force, Axial displacement in compression, Optic decentration, Optic tilt, Angle of contact, Compression force decay, Dynamic fatigue durability, Loop pull strength, Surface and Bulk homogeneity)					
3	Optical Tests					
4	Dioptric power					
5	MTF test					
6	Resolution Efficiency Test					
B	Chemical					
1	ETO Residual Test					
C	Biological					
1	Sterility test					
2	Pyrogen / Bacterial Endotoxins Test					
60	S-89	Disposable Sterile	Pair			

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
	(a), (b)	Surgical Rubber Gloves Size 8 Inches Should Conform to IS 13422		1	Dimension	
				a	Length	
				b	Width	
				2	Thickness	
				a	Finger	
				b	Palm	
				c	Cuff	
				3	Tensile Strength (Mpa) (Before Ageing)	
				4	Tensile Strength (Mpa) (After Ageing)	
				5	Elongation at break (%) (Before Ageing)	
				6	Elongation at break (%) (After Ageing)	
				7	Stress at 500% (Mpa) (Before Ageing)	
				8	Air Tight Test	
				B	Biological Test	
				1	Sterility	
61	S-90 (a), (b), (c), (d)	Rubber examination gloves made of natural rubber latex. Non-sterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Should Conform to IS 15354	Dispenser Box of 100 Gloves	1	Dimension (Length, width)	
				2	Thickness of Palm	
				a	Smooth Surface	
				b	Textured Surface	
				3	Thickness of Finger	
				a	Smooth Surface	
				b	Textured Surface	
				3	Tensile Strength (Mpa) (Before Ageing)	
				4	Tensile Strength (Mpa) (After Ageing)	
				5	Elongation at break (%) (Before Ageing)	
				6	Elongation at break (%) (After Ageing)	
				7	Stress at 500% (Mpa) (Before Ageing)	
				8	Water tightness	
62	S-91	Pressure Monitoring Line / High Pressure Extension Line	Each piece in Blister Pack	A	Physical	
				1	Description	
				2	Length of Tube	
				3	Width of Tube	
				4	Pressure	
				5	Transparency	
				6	Particulate Contamination	
				7	Components	
				8	Leakage	
				9	Tensile strength	
				B	Chemical	
				1	Appearance of extract	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				2	Acidity or Alkalinity	
				3	UV abs of extract	
				4	Buffering capacity	
				5	Reducing (Oxidizable) Substance	
				6	Metal ions	
				7	Non Volatile Residue	
				B	Biological	
				1	Sterility	
				2	Toxicity	
				3	Pyrogen / Bacterial Endotoxins Test	
63	S-92	Urine Collecting Bag for new born / Paediatric urine collecting Bag	Each piece	A	Physical	
				1	Description	
				2	Components	
				3	Total Bag Length	
				4	Width	
				5	Leakage	
				B	Biological Test	
				1	Sterility	
				2	Toxicity	
				3	Pyrogen / Bacterial Endotoxins Test	
64	S-93	Umbilical Catheter (for New Born) – All sizes	Each piece	A	Physical	
				1	Description	
				2	Dimensions	
				3	Components	
				4	Length	
				5	Integrity	
				B	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
65	S-94	Umbilical Cord Clamp	Each piece	(A)	Physical	
				1	Description	
				2	Components	
				3	Surface Finish	
				4	Length	
				5	Marking	
				6	Particulate Matter	
				B.	Biological Test	
				1	Sterility	
66	S-95	Absorbable Regenerated Cellulose Sheet net size 2"X3" with surgical sponze	Each piece	A	Physical	
				1	Dimensions (Length, width)	
				2	Absorbability	
				B	Chemical test	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				1	Carboxylic acid content test	
				C	Biological Test	
				1	Sterility	
				2	Microbial examination test	
67	S-96 (a), (b)	Close wound Drainage Device under negative pressure · Closed wound suction unit Catheter 16FG, 18FG	Each piece	A	Physical	
				a	Container	
				1	Capacity	
				2	Negative Pressure	
				b	Connecting Tube	
				1	O.D. of Tube	
				2	Length of Tube	
				c	Perforated Tube	
				1	O.D. of Tube	
				2	Length of Tube	
				3	Radio opaque line	
				4	Quality of Perforation & No. of Eyes	
				5	Strength of Joints	
				6	Blockage test	
				d	Perforated Tube with Needle	
				1	O.D. of Needle	
				2	Length of Tube	
				3	Length of Needle	
				4	Needle point	
				e	Performance Test	
				1	Resistance to Deformation	
				2	Force at Break	
				3	Leakage Test	
				B	Chemical Test	
				1	Corrosion Test	
				C	Biological Test	
				1	Sterility	
68	S-97	T – Tube for Common Bile Duct Drainage	Each piece	A	Physical	
				1	Description	
				2	Dimensions	
				3	Performance	
				B	Chemical test	
				C	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
69	S-98	Bone Cement with antibiotics fast & slow setting	40 gm Pack	A	Physical	
				1	Description	
				2	Identification	
				3	Weight	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				4	Setting Time	
				B	Chemical test	
				C	Biological Test	
70	S-99(a)	Sanitary Napkin, Beltless IS 5405	6 napkins per pack	1	Description	
				2	Dimensions	
				3	Type	
				4	Overall Length	
				5	Core Length/Pad length	
				6	Width	
				7	Core Width/Pad Width	
				8	Thickness	
				9	Weight	
				10	pH	
				11	Absorbent Core	
				12	Barrier or Bottom Sheet	
				13	Total Viable Count	
				14	S.Aureus	
				15	Absorbency	
				16	Packing and Labelling	
71	S-99(b)	Sanitary Napkin, Belt-type IS 5405	6 napkins per pack	1	Description	
				2	Absorbing Pad length	
				3	Dimensions	
				4	Core Length	
				5	Width	
				6	Thickness	
				7	Weight	
				8	Pack	
				9	Elastic Belt with loops	
				10	pH	
				11	Absorbent Core	
				12	Barrier or Bottom Sheet	
				13	Absorbency	
				14	Total Viable Count	
				15	S.Aureus	
				16	Packing and Labelling	
72	S-99(P)	Belt-less Sanitary Napkin with wings	6 napkins per pack	1	Description	
				2	Dimensions	
				3	Overall Length	
				4	Full Core /Pad Length	
				5	Full Core /Pad Width	
				6	Total Width (With Wings)	
				7	Thickness	
				8	Weight	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				9	Type	
				10	pH	
				11	Absorbency	
				12	Cover /Top Sheet	
				13	AbsorbentCore	
				14	Barrier or Bottom Sheet	
				15	Total Viable Count	
				16	S.Aureus	
				17	Packing and Labelling	
73	S-100 & S-101	Oxygen Mask (Adult/Paediatric) (S-100/S-101)	Unit	1	Description	
				2	Softness of Mask	
				3	Length of Tube	
				4	Leakage from Joint	
				5	Components	
				6	Elastic strap	
				7	Aluminium clip	
				8	Sterility	
74	S-102	Sterile Catheter, single Use, for Urinary Drainage (Foley Baloon Catheter), 2 way, Size 14	Each Piece	A	Physical	
				1	Description	
				2	Shape and dimensions	
				3	Wall of Thickness	
				4	Length of catheter	
				5	Valve	
				6	Ballon Capacity	
				7	Diameter of Cathater	
				8	Tensile strength of rubber	
				9	Elongation at Break	
				10	Balloon Leakage	
				B	Chemical test	
				1	pH of water extract	
				2	Extractable Colour	
				3	Heavy metals	
				C	Biological Test	
				1	Sterility	
75	S-103	Nelaton Catheter Size 14FG	Each Piece	1	Tube Length	
				2	Components	
				3	Catheter Tip	
				4	Effective length	
				5	O.D. of Tube	
				6	Strength of Joints	
				7	Heavy metals	
				8	Non Volatile Residue	
				9	Buffering Capacity	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				10	Presence of Radio opaque line	
				11	Joint test of tube and Connector	
				12	Surface Finish	
				13	Corrosion Test	
				14	Sterility Test	
				15	BET Test	
				16	Leakage test of joint	
76	S-104	ECG Electrode •Reliable trace, •High conductivity,• Easy to handle				
77	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. • Should conform to IS 3319		A	Physical	
				1	Shape and Dimensions	
				2	Thickness	
				3	Hardness test	
				4	Visual Examination (particularly for nicks)	
				5	Performance Test	
				B	Biological Test	
				1	Sterility	
78	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• Shall conform to 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. IS-12050	Each Piece	A	Physical	
				1	Description	
				2	Scale Marking	
				3	Length /Interval	
				4	Hub Colour and Size of Needle	
				5	Finger Grips and Piston	
				6	Leakage Test	
				7	Detachable Needle Hub	
				8	Bond-Hub/ Barrel /Needle	
				B	Chemical Test	
				1	Appearance of extract	
				2	Acidity or Alkalinity	
				C	Biological Test	
				1	Sterility	
79	S-107	Urethral Catheter 90 (FG-14), made up of medical grade PVC		1	Description	
				2	Particulate Matter	
				3	Printed Matter	
				4	Integrity of Package	
				5	Components	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				6	Leakage from Joints	
				7	BET	
				8	Sterility	
80	S-108	Urethral Catheter 91 (FG-10), made up of medical grade PVC		1	Description	
				2	Particulate Matter	
				3	Printed Matter	
				4	Integrity of Package	
				5	Components	
				6	Leakage from Joints	
				7	BET	
				8	Sterility	
81	S-109	Vaccum Suction Set, 2.5 meter Length, •Suction handle with Suction Tube•Sterile, • Pyrogenic Free, •Latex free,• Single use		1	Description	
				2	Particulate Matter	
				3	Components	
				4	Leakage from Joints	
				5	BET	
				6	Sterility	
82	S-110	Epidural Minipack 18G, 90 mm, Metal Stylet For Single Use only, •Sterile, •Epidural catheter 20G, L 90 cm,•6 Lateral Holes closed end, •Borst Adapter•Epidural Catheter Flat filter 0.2 micro meter •Thread Assist Guide•LOR (Loss of resistance) Plastic Syringe 6 ml		1	Description	
				2	Particulate Matter	
				3	Components	
				4	Leakage from Joints	
				5	Gas Mixture	
				6	BET	
				7	Sterility	
				8	Toxicity	
83	S-111	Vascular Catheter with metal Guide No. 16, Double Lumen Size 30 cm (Longline IV.)				
84	S-112	Vascular Catheter with metal Guide No. 18 Double Lumen Size 30 cm (Longline IV.)				
85	S-113	Vascular Catheter with metal Guide No. 20 Double Lumen Size 30 cm (Longline IV.)				
86	S-114	Vascular Catheter with metal Guide No. 22 Double Lumen Size 30 cm (Longline IV.)				
87	S-115	Vascular Catheter with metal Guide No. 16 Double Lumen Size 45 cm (Longline IV.)				

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
88	S-116	Vascular Catheter with metal Guide No. 18 Double Lumen Size 45 cm (Longline IV.)				
89	S-117	Vascular Catheter with metal Guide No. 20 Double Lumen Size 45 cm (Longline IV.)				
90	S-118	Vascular Catheter with metal Guide No. 22 Double Lumen Size 45 cm (Longline IV.)				
91	S-119	3 Way Stop Cock , Non Pyrogenic & Single Use, should be leak proof, with smooth movements		1	Description	
				2	Particulate Matter	
				3	Components	
				4	Leakage from Joints	
				5	Flow Rate	
				6	Baeterial Endotoxin	
				7	Sterility	
				8	Non Volatile Residue	
				9	Residue on Ignition	
				10	Heavy Metals	
				11	Buffering Capacity	
92	S-120	3 Way Stop Cock with extension Tube (Vein -O-Line) size 10 cm(Non Pyrogenic & Single Use)		1	Description	
				2	Particulate Matter	
				3	Components	
				4	Leakage from Joints	
				5	Flow Rate	
				6	Baeterial Endotoxin	
				7	Sterility	
				8	Non Volatile Residue	
				9	Residue on Ignition	
				10	Heavy Metals	
				11	Buffering Capacity	
93	S-121	3 Way Stop Cock with extension Tube (Vein -O-Line) size 50 cm(Non Pyrogenic & Single Use)		1	Description	
				2	Particulate Matter	
				3	Components	
				4	Leakage from Joints	
				5	Flow Rate	
				6	Baeterial Endotoxin	
				7	Sterility	
				8	Non Volatile Residue	
				9	Residue on Ignition	
				10	Heavy Metals	
				11	Buffering Capacity	
94	S-122	3 Way Stop Cock with extension Tube (Vein -O-		1	Description	
				2	Particulate Matter	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
		Line) size 100 cm (Non Pyrogenic & Single Use)		3	Components	
				4	Leakage from Joints	
				5	Flow Rate	
				6	Baeterial Endotoxin	
				7	Sterility	
				8	Non Volatile Residue	
				9	Residue on Ignition	
				10	Heavy Metals	
				11	Buffering Capacity	
95	S-123	3 Way Stop Cock with extension Tube (Vein -O-Line) size 150 cm (Non Pyrogenic & Single Use)		1	Description	
				2	Partculate Matter	
				3	Components	
				4	Leakage from Joints	
				5	Flow Rate	
				6	Baeterial Endotoxin	
				7	Sterility	
				8	Non Volatile Residue	
				9	Residue on Ignition	
				10	Heavy Metals	
				11	Buffering Capacity	
96	S-124	Abdominal Drain Kit, Sterile, having drainage catheter and Collection Bag (2000 ml) (size 16)• 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		1	Description	
				2	Transparency	
				3	Kink resistant and flexible tube	
				4	Length	
				5	Width	
				6	Particulate Matter	
				7	Components	
				8	Leakage of Bag	
				9	Capacity	
				10	O.D of catheter	
				11	O.D. of Tube	
				12	Rounded open distal end with smooth atraumatic eyes in catheter catheter with marking at 2cm in interval	
				13	Non-return valve	
				14	Graduation	
				15	Total length of tubing	
				16	Radio opaque line	
				17	BET	
				18	Sterility	
97	S-125	Abdominal Drain Kit, Sterile, having drainage catheter and Collection Bag (2000 ml) (size 20)• Graduated Bag• Should		1	Description	
				2	Transparency	
				3	Kink resistant and flexible tube	
				4	Length	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder	
		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		5	Width		
				6	Particulate Matter		
				7	Components		
				8	Leakage of Bag		
				9	Capacity		
				10	O.D of catheter		
				11	O.D. of Tube		
				12	Rounded open distal end with smooth atraumatic eyes in catheter catheter with marking at 2cm in interval		
				13	Non-return valve		
				14	Graduation		
				15	Total length of tubing		
				16	Radio opaque line		
				17	BET		
				18	Sterility		
98	S-126		Nasal Prong Neonatal (Flexible Medical Grade, 2 Meter Long, Multichannel Kink Resistance Tube		1	Description	
					2	Particulate Matter	
					3	Integrity of Package	
					4	Components	
				5	Leakage from Joints		
				6	BET		
				7	Sterility		
99	S-127	Elastic Adhesive Bandage BP 1m x 10cmAdhesive material should have good quality sticking property, non-allergic	Each Piece	1	Description		
					2	Zinc Oxide Content in Adhesive Mass%	
					3	Elasticity	
					4	Weight of Adhesive massg/sq.m	
					5	Weight per unit area	
					6	Fabric fiber identification	
					7	Fabric weight g/sq.m	
					8	Threads per 10 cm (warp, weft)	
100	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)		A	Physical		
				1	Description		
				2	Dimensions (outside diameter, effective length)		
				3	Surface (free from extraneous matter)		
				4	Integrity		
				5	Force at Break		
				6	Freedom from liquid leakage under pressure		
				7	Freedom from air leakage into hub assembly		
				8	Needle and fittings		
				9	Flow rate		

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				10	Needle properties (material, design, needle point, needle hub, strength of union between hub and needle tube)	
				11	Vent fitting (Test for liquid leakage from vent fitting)	
				B	Chemical Test	
				1	Acidity or Alkalinity	
				2	Corrosion Resistance	
				C	Biological Test	
				1	Sterility	
				2	Pyrogen / Bacterial Endotoxins Test	
				3	Toxicity	
101	S-129	NIV Mask (Noninvasive Ventilation Mask) Adult- Should be light weight silicon based full face & nasal mask with face & forehead soft cushion pads 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		1	Identification of Polymer (by FTIR)	
				2	Weight of the mask without head gear and clips	
				3	Weight of the mask with head gear and clips	
				4	Dead volume space internal width and Height	
				5	Gripper	
				6	Sampling two port present	
				7	Brittleness test (for silicone)	
				8	F.Port	
				9	Bronchoscopy Port	
				10	Size	
				11	Head Strap	
				12	Non Allergic and Leak Proof	
				13	Adoption to Wear Different Face	
102	S-130	NIV Mask (Noninvasive Ventilation Mask) Adult- Should be light weight silicon based full face & nasal mask with face & forehead soft cushion pads for adults in Medium 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		1	Identification of Polymer (by FTIR)	
				2	Weight of the mask without head gear and clips	
				3	Weight of the mask with head gear and clips	
				4	Dead volume space internal width and Height	
				5	Gripper	
				6	Sampling two port present	
				7	Brittleness test (for silicone)	
				8	F.Port	
				9	Bronchoscopy Port	
				10	Size	
				11	Head Strap	
				12	Non Allergic and Leak Proof	
				13	Adoption to Wear Different Face	
103	S-131	NIV Mask (Noninvasive Ventilation Mask) Adult- Should be light weight silicon based full face & nasal mask with face & forehead soft cushion pads for adults in Large		1	Identification of Polymer (by FTIR)	
				2	Weight of the mask without head gear and clips	
				3	Weight of the mask with head gear and clips	
				4	Dead volume space internal width	

Sr. No	Code No.	Item Description	Unit	Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder	
		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		and Height		
				5 Gripper		
				6 Sampling two port present		
				7 Brittleness test (for silicone)		
				8 F.Port		
				9 Bronchoscopy Port		
				10 Size		
				11 Head Strap		
				12 Non Allergic and Leak Proof		
				13 Adoption to Wear Different Face		
104	S-132		NIV Mask (Noninvasive Ventilation Mask) Adult· Should be light weight silicon based full face & nasal mask with face & forehead soft cushion pads 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		1 Identification of Polymer (by FTIR)	
					2 Weight of the mask without head gear and clips	
					3 Weight of the mask with head gear and clips	
				4 Dead volume space internal width and Height		
				5 Gripper		
				6 Sampling two port present		
				7 Brittleness test (for silicone)		
				8 F.Port		
				9 Bronchoscopy Port		
				10 Size		
				11 Head Strap		
				12 Non Allergic and Leak Proof		
				13 Adoption to Wear Different Face		
105	S-133	NIV Mask (Noninvasive Ventilation Mask) Paediatric· Should be light weight silicon based full face & nasal mask with face & forehead soft cushion pads in Small size. · Should be with ergonomically designed clips/straps for easy disengagement of the head gear· Should be Single Use with Bronchoscopy and CO2 &O2 port with chin support · Non allergic, leak proof, contour should be maintained		1 Identification of Polymer (by FTIR)		
				2 Weight of the mask without head gear and clips		
				3 Weight of the mask with head gear and clips		
				4 Dead volume space internal width and Height		
				5 Gripper		
				6 Sampling two port present		
				7 Brittleness test (for silicone)		
				8 F.Port		
				9 Bronchoscopy Port		
				10 Size		
				11 Head Strap		
				12 Non Allergic and Leak Proof		
				13 Adoption to Wear Different Face		
106	S-134	Nebulization Mask Adult		1 Description		
				2 Identification of Polymer in material		
				3 Chamber Height		
				4 Toxicity Identification of polymer in Tube		

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				5	Dimension of Tube (Length & Width)	
				6	Size of Mask	
107	S-135	Nebulization Mask Paediatric		1	Description	
				2	Length	
				3	Width	
				4	Tube	
				5	Identification of Polymer in material	
				6	Chamber Height	
				7	Toxicity Identification of polymer in Tube	
				8	Dimension of Tube (Length & Width)	
				9	Size of Mask	
108	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.				
109	S-137	Chemotherapy Port & Non-coring needles (Paediatric). Valved 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.				
110	[NE32 A]	Bed Side Leucodepletion filters for blood Transfusion (For 1 Unit of Red Cell) [NE32A]				
111	[NE32 B]	Bed Side Leucodepletion filters for blood Transfusion (For 1 Unit of Red Cell) [NE32B]				
76	R-1 To R-57 and R-61 to 80	Sutures (Sterilized Surgical Needled Sutures) USP / BP		A	Physical	
				1	Description	
				2	Length	
				3	Diameter	

Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)	Test parameters proposed to be carried out by bidder
				4	Tensile Strength (for USP)	
				5	Minimum Breaking Load (for BP)	
				6	Needle Attachment	
				B	Tests for Needle	
				7	Needle description	
				8	Size	
				9	Shape	
				10	Dimension	
				11	Flexibility	
				12	Sharpness	
				13	Smoothness and finish	
				B	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	
				C	Biological Test	
				1	Sterility	

NOTE:-

- * The parameters of testing of sutures will be as per the respective pharmacopoeia.
- * The above tests are minimum tests to be performed.
- * For item code R-68 to R-74 bidders should quote the rates including Antibacterial test.

ANNEXURE –IX
Ref: Clause no. 3 (p)

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

A - General requirements and premises

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

B- Personal & Equipment

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

Chemicals and Reagents, Good housekeeping and safety

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

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

S.N.	Details of the requirement	Remark
1	All equipments, instruments and other devices used in the laboratory shall use appropriate methods and procedures for all tests or calibrations and they shall be regularly Calibrated and validated.	
2	For most of the equipments and instruments, SOP for calibration and calibration schedule be the laboratory and a logbook shall also be prepared by each laboratory for proper documentation of calibrations results.	

3	Reference material shall be traceable to agency authorized by Government of India or any other International body.	
4	The laboratory shall prepare working standard by comparing with the reference standards and shall be routinely checked for their purity.	
5	Whenever, any new reference material is received by the laboratory following details are to be written - a- Source of supply ; b- Code number of the reference material ; c- Date of receipt ; d- Batch number or identification number of the supplying agency ; e- Details like assay value, water content or information provided ; f- Storage condition of the material ; g- Date of expiry, if any and date of manufacturing if possible.	
6	SOP for maintenance of microbial culture and sub-culture must be prepared by the laboratories ;	

Quality system : & internal quality audits, management review :

S.N.	Details of the requirement	Remark
1	The measurements and calibrations shall fully conform to the compendia requirements and the method demonstrably based on validation protocols are followed.	
2	Remedial action o the observations by internal and external audits are taken appropriately	
3	Documented quality policy for the organization.	
4	Internal audits are done to assure the integrity of the analysis ad such audits shall be conducted periodically	
5	Each activity is audited at least once in a year.	
6	The quality manager shall maintain all the records of the analysis being conducted which includes test system, the type of analysis , date on which analysis is done	
7	Review yearly 1- Report or input 2- Matter arising from previous reviews ; 3- Report of external audits, if any ; 4- Surveillance report, if any ; 5- Result of proficiency testing ; 6- Complaints or feedback received from users 7- Details of in-house quality control checks ; 8- Need of amendment of the quality system and documentation ; 9- Introduction training of new staff.	

Standard operating Procedures

S.N.	Details of the requirement	Remark
1	Shall be written in a chronological order listing different steps leading to an analysis of drugs or calibration of an instruments ;	
2	Shall have SOP manuals and have periodic Review.	
3	Standard Operation Procedures for the followings are required (i) Sample handling and accountability ; (ii) Receipt identification, storage, mixing and method sampling of the test	

S.N.	Details of the requirement	Remark
	and control articles ; (iii) Record keeping, reporting, storage and retrieval of data ; (iv) Coding of different studies, handling of data including use of computerized data system ; (v) Operation of technical audit personnel in performing and reporting audits, inspections and final report reviews ; (vi) Routing inspection of cleaning maintenance, testing, calibration and standardization of instruments ; (vii) Action to be taken in respect of equipment failure ; (viii) Analytical data methods (ix) Health and safety protection ; (x) Date handling and storage retrieval ; (xi) Health and safety protection ; (xii) Animal room preparations ; (xiii) Animal care ; (xiv) Storage and maintenance of microbial cultures ; (xv) Maintenance of sterility room (i.e. constant maintenance and monitoring of Aseptic condition room) ; (xvi) Use and storage of reference standards ; (xvii) Procurement of stores and equipment ; (xviii) Monitoring of testing of samples ; (xix) Method of retention of unexpended samples, their location, maintenance and disposal ; (xx) Document control ; (xxi) Redressal of technical complaints ; (xxii) House- keeping (xxiii) Corrective and preventive action ; (xxv) Calibration manual. (xxvi) Training manual.	
4	Protocols and specification archive :- List of all the pharmacopeias a file on patent and proprietary medicines (non-Pharmacopeia) test methods to specification prepared and validated by the manufacturer. The test methods shall be submitted to the concerned Drug Control Authority.	
5	Raw data - Date integrity and security shall be maintained Original entry must be saved and the system shall trail for all data.	
6	Storage and archival ; The residual sample shall be retained in proper storage condition for a period of one year after the final report.	
7	The laboratory must establish and maintain procedures for the identification collection, indexing, retrieval, storage, maintenance, and Disposal of all quality documents.	
8	All the raw date, documentation, SOP, protocols and final reports are the be retained and there shall be archives of orderly storage and expeditious retrieval of all raw data, documentation, protocols, interim and final report.	
9	The condition under which the original documents are stored must ensure	

S.N.	Details of the requirement	Remark
	their security and confidentiality.	
10	Raw data on thermal paper might fade 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:

Form of Bid-Securing Declaration
(On Rs. 50.00 Stamp)

Date:

Bid No. :

Alternative No. :

To:

We, the undersigned, declare that:

We understand that, according to your conditions, bids must be supported by a Bid-Securing Declaration.

We accept that we are required to pay the bid security amount specified in the Term and Condition of Bid,

in the following cases, namely :-

- (a) when we withdraw or modify our bid after opening of bids;
- (b) when we do not execute the agreement, if any, after placement of supply/work order within the specified period;
- (c) when we fail to commence the supply of the goods or service or execute work as per supply/work order within the time specified;
- (d) when we do not deposit the performance security within specified period after the supply/work order is placed; and
- (e) if we breach any provision of code of integrity prescribed for bidding specified in the Act and

Chapter VI of these rules.

In addition to above, the State Government shall debar us from participating in any procurement process undertaken for a period not exceeding three years in case where the entire bid security or any part thereof is required to be forfeited by procuring entity.

We understand this Bid Securing Declaration shall expire if:-

- (i) we are not the successful Bidder;
- (ii) the execution of agreement for procurement and performance security is furnished by us in case we are successful bidder;
- (iii) thirty days after the expiration of our Bid.

(iv) the cancellation of the procurement process; or
(v) the withdrawal of bid prior to the deadline for presenting bids, unless the bidding documents

stipulate that no such withdrawal is permitted.

Signed.: -----

Name :-----

In the capacity of :-----

Duly authorized to sign the bid for and on behalf of:

Dated on day of

Corporate Seal -----

[Note: In case of a Joint Venture, the Bid Securing Declaration must be signed in name of all partners of the Joint Venture that is submitting the bid.]