RAJASTHAN MEDICAL SERVICES CORPORATION LTD.

Dated: 26.07.2017

(A Govt. of Rajasthan Undertaking)

Gandhi Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India Tel No: 0141-2228066, 2228064, E-mail: rmsc@nic.in, edprmsc@gmail.com

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF SURGICAL & SUTURES FOR THE YEAR 2017-2019 (Ending on 30.09.2019)



!! सर्वे सन्तु निरामयाः!!

LAST DATE OF SUBMISSION OF ONLINE BIDS:28-08-2017

Ministry of Health & Family Welfare Government of Rajasthan

RMSCL

"Mukhyamantri Nishulak Dava Yojana"

'D' Block, Swasthya Bhawan, Tilak Marg, Jaipur – 302005, India
Tel No: 0141-2228066, 2228064, E-mail: edprmsc@gmail.com

Ref. No F.02(45)/RMSCL/Proc/LABEMPANELMENT(S&S)/NIB-7/2017/265 Dated:26.07.2017

Notice Inviting E-Bids

E-bids are invited upto 1.30 PM of 28.08.2017 from approved Drugs Testing Laboratories situated in India for analysis of Surgical & Sutures for the year 2017-19 (ending on 30.09.2019) (UBN NO-----------------------).(Estimated Cost 50 lacs). Details may be seen in the Bidding Documents at our office or at the website of State Public procurement Portal http://sppp.raj.nic.in, www.dipronline.org, http://eproc.rajasthan.gov.in., www.rmsc.health.rajasthan.gov.in and may be downloaded from there.

Executive Director (Procurement)
RMSCL

RAJASTHAN MEDICAL SERVICES CORPORATION LTD. RAJASTHAN

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF SURGICAL AND SUTURES FOR THE YEAR 2017-2019 (Ending on 30.09.2019)

Bid Reference: : F.02(45)/RMSCL/Proc/LAB

EMPANELMENT(S&S)/NIB-7/2017/265 dated:26.07.017

Pre- bid conference **03.08.2017** at **11:30** A.M.

:

:

(RMSCL meeting Hall)

Date and time for downloading

bid document

: 26.07.2017 from 06.00 PM

Last date and time of submission

of online bids

28.08.2017 at 1.30 PM

Date and time of opening of

Online technical bids

28.08.2017 at 2.30 PM

Cost of the Bid Document : Rs. 2000/-

RISL Processing Fees : Rs. 1000/-

Bid Security : Rs. 100000/-

RAJASTHAN MEDICAL SERVICES CORPORATION LTD. RAJASTHAN

E-BID FOR THE EMPANELMENT OF ANALYTICAL TESTING LABORATORIES FOR THE TEST AND ANALYSIS OF SURGICAL & SUTURES FOR THE YEAR 2017-2019 (Ending on 30.09.2019)

"CONFIDENTIALITY IS THE ESSENCE OF THIS BID"

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

- a) E-Bids In Two Separate Bids (Technical Bid & Price Bid)] Will Be Received Till 1.30 PM on 28.08.2017 By The Rajasthan Medical Services Corporation Ltd, For The Empanelment Of Analytical Testing Laboratories For The Test And Analysis Of SURGICAL & SUTURES For The Year 2017-2019 (Ending on 30.09.2019)
- b) The bids shall be valid for a Period of 120 days from the date of opening of Technical Bid and prior to the expiration of the bid validity the Bid Inviting Authority may request the Bidders to extend the bid validity period for an additional specified period of time. The Bidder may refuse extension of bid validity, and in such a case its Bid security shall not be forfeited
- c) The e-Bids will be received on web-portal of e-procurement of Government of Rajasthan. Every Bidder will be required to pay the Bid form fee Rs. 2000.00 for downloaded from the website, Bid Security as applicable in Bid condition no. 6 and processing fee of Rs.1000.00 of RajCom Info Services Limited (R.I.S.L.) through separate prescribed challans (format enclosed in Annexure I) in any branch of the Punjab National Bank Account No 2246002100024414 throughout country up to 27.08.2017 or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSCL by 1:30 PM on 28.08.2017 Bid Security Deposit in any other form will not be accepted. The bidders shall submit/upload scanned copy of all the e-generated receipt in Technical Bid. In the absence of Bid fees and processing fees and Bid Security the Bids will be rejected.

2 Eligibility Criteria for Empanelment :-

(1) Drug Testing Laboratories should have valid Approval for carrying out test on drugs under the Drugs and Cosmetics Act, 1940 and Rules there under, with three years standing in **Drugs**, **Chemicals**, **Food and Other Items**. The lab shall be entitled for empanelment for the categories of items for which lab is

- having approval. Bid is invited from approved Drugs 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 NABL accreditation with proper scope of accreditation to undertake testing of drugs, surgical and sutures.
- (3) The laboratory should have an average annual turnover of **not** less than **Rs. 50 Lakhs** for past preceding three years (2013-14, 2014-15, 2015-16 or 2014-15, 2015-16, 2016-17).
- (4) The lab should have undertaken test and analysis of surgical & sutures or drugs and supplies of similar nature of at least three government institutions/corporation/reputed manufacturers of medicines / medical devices, Surgical & Sutures formulations.
- (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.
- (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 mention type of test for each item to be carried out by him, the filled up annexure VII to be submitted with technical bid.

- (b) The bidders shall submit/upload scanned copy of e-generated receipt in Technical Bid deposited for Bid fees, RISL processing fee and Bid Security.
- 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)/Copy of NABL accreditation with proper scope for testing of surgical & sutures.
- e) Documentary evidence of having analysed Drugs, Chemicals, Food and Other Items for the last three years with a statement in the Performa as given in Annexure III.
- **f**) Attested copy of certificate of registration for **GST**.
- **g)** Non- Conviction Certificate by the State Licensing Authority/ competent authority.
- h) Annual turnover statement for 3 year i.e. 2013-14, 2014-15, 2015-16 or 2014-15, 2015-16, 2016-17 certified by the practicing Chartered Accountant.
- i) Copies of the Balance Sheet and Profit and Loss Account for three years i.e. 2013-14, 2014-15, 2015-16 or 2014-15, 2015-16, 2016-17 duly 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 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, wherever required.
 - e) In the case of Products not falling in pharmacopoeia Drug & Cosmetics Act 1940 and Rules 1945, BIS etc. the Method of Analysis Should be appended to the Report, especially if the sample is declared as "not of standard quality".
- **k**) A declaration in the Performa given in Annexure V duly signed and Notarized.

- 1) 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.

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 coated separately at last entry of BOQ.

5 OPENING OF TECHNICAL AND FINANCIAL EVALUATION

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

6 BID SECURITY

The Bid Security shall be Rs.100000/-. The Bid Security shall be paid in through separate prescribed challans (format enclosed in Annexure I) in any branch of the Punjab National Bank Account No 2246002100024414 throughout country up to 27.08.2017 or through D.D. / bankers cheque in favour of M.D. RMSCL physically in the office of RMSCL by 1:30 PM on 28.08.2017 Bid Security in any other form will not be accepted. The bidders shall submit/upload scanned copy of all the e-generated receipt in Technical Bid. In the absence of Bid fees and processing fees and Bid Security the Bids will be rejected.

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

Government undertaking/ PSU are exempted for Bid Security 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 for 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. 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.

9. AGREEMENT

- The agreement with empanelled laboratories will remain valid up to 30.09.2019.
 This may be further extended for a further period of three months with mutual consent.
- 2. All 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 form 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 deposit performance security @ 5% of contract value 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 prescribed under Drugs & Cosmetics Act/BIS etc., (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.

- 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 final results and reason for failure should be highlighted by pink / red highlighters.
- 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 RMSCL in triplicate. In case of failure of a sample, the result should be communicated immediately to the Executive Director (Q.C.) through phone / E-mail and the report should be sent along with protocol.
- 3. If in any circumstances (like break down of instrument, non-availability of reference standard etc.) the Analytical Laboratory is unable to undertake analysis for a sample, the same should be reported within 24 hours of receipt of such a sample by phone or E-mail and the sample should be returned to the Executive Director (Quality Control), Rajasthan Medical Services Corporation Limited, Jaipur after taking necessary telephonic or mail consent. In case of inability of laboratory to undertake the testing, a penalty of 25% of testing charges applicable for that product / products will be recovered.
- 4. If standard test procedure of any product is required the same should be demanded within 48 hours from date of receipt of sample. Period lapsed/taken in providing 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 Executive Director (Quality Control), Rajasthan Medical Services Corporation Limited Jaipur by 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 RMSCL Headquarters.
- 8. It will be sole discretion of RMSCL to allot the samples to any empanelled lab in case when there are more than one lab approved for an item.

12. PAYM ENT 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 Surgical & Sutures 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 performance security within the time specified or withdraws the bid after intimation of the acceptance of the bid has been sent to or owing to any other reasons, he is unable to undertake the contract, the empanelment will be cancelled and the Bid security deposited by the Bidder shall stand forfeited in favour of the Rajasthan Medical Services Corporation Limited. Such

- Bidder(s) will also be liable for all damages sustained by the Rajasthan Medical Services Corporation Limited due to of breach of bid conditions. Such damages shall be assessed by the Managing Director, Rajasthan Medical Services Corporation Limited whose decision shall be final.
- 2. Non performance of any bid or empanelment conditions will disqualify a laboratory to participate in the bid for the period as decided by RMSCL.
- 3. If it is revealed that the analytical Laboratory is involved in any form of fraud and collusion with the suppliers of Rajasthan Medical Services Corporation Limited, the Analytical Laboratory will be black listed for a period considered suitable. The Bidders shall also be liable for action under criminal law and the matter will be notified to the concerned Director of Drugs Control for suitable action against them under Drugs & Cosmetics Act & Rules.
- 4. The Managing Director, Rajasthan Medical Services Corporation Limited will be at liberty to terminate without assigning any reasons, the empanelment of any laboratory either wholly or in part at one month 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)/ 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 up to 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 <u>furnish the test report</u> 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 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 authorized representative.

vi. Fee for filling appeal

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

vii. Procedure for disposal of appeal

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

- (ii) Peruse or inspect documents, relevant records or copies thereof relating to the matter.
- (c) After hearing the parties, perusal or inspection of documents and relevant records or copies thereof relating to the matter, the Appellate Authority concerned shall pass an order in writing and provide the copy of order to the parties free of cost.
- (d) The order passed under sub-clause (c) above shall be placed on the State Public procurement Portal.

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

Any person participating in 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 behavior to impair the transparency, fairness and progress of the procurement process;
- d) Not misuse any information shared between the procuring Entity and the Bidders with an intent to gain unfair advantage in the procurement process;
- e) Not include 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-incharge/ consultant for the contract.

18. JURISDICTION

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

Managing Director Rajasthan Medical Services Corporation

Acknowledgement		Address for communication	Signature	Name of the Depositor	Amount (in words): ₹	Coins * Total	5 *	50 * 20 *	500 *	iomination ₹	Cash Deposit:	Mobile No.			Supplier Name	SELIGATIS SELLACIO SILVESIO		Institute ID R	Institute Name Ra	Branch	i.	AULION: USE FO	ATITION - TISE "FC"
Cashier/Officer	For Bank use only	ation				Total amount	Total fee payable ₹ 0 0 0 0 0 - 0 0			Ps Chq No Date of Chq Name of Bank ₹ Ps	Cheque Deposit:		Select any one out of - Tender Fees/EMD/SD/Tender Processing fees/Others			DD MM XX		RMSCJ - A/c No. 2246002100024414	Rajasthan Medical Services Corporation, Jaipur		punjab national bank DIST. NO.	Bank Copy	A TITION . TISE "ECMRR" MENTI OPTION IN FINACLE INSTEAD OF "TM"
Acknowledgement		Address for communication	Signature	Name of the Depositor	Amount (in words): ₹	Total	5 *	20 *	100 *	ation	Cash Deposit:	Mobile No.	Type of Deposit	Tender Ref. No.	Supplier Name	DETAILS OF THE SUPPLIER		Institute ID	Institute Name	Branch	7		
t Cashier/Officer	For Bank use only	nunication		sitor): ₹		Commission ₹ 0 0 0 0 0 - 0 0	Total for navable ₹		The Chq No Date of Chq Name of Bank (1's			Select any one out of - Tender Fees/EMD/SD/ Tender Processing fees/Others				Date of Deposit DD MM YY	RMSCJ - A/c No. 2246002100024414	Rajasthan Medical Services Corporation, Jaipur		punjab national bank DIST. NO.	Customer Copy	

ANNUAL TURN OVER STATEMENT

T	The Annual Turnover (for drugs	and medicines inclu	ding Surgical and sutures
testing s	for the past		
three yea	ars are given below and certified	that the statement is to	rue and correct.
S.No.	Years	Turnov	ver in Lakhs (Rs)
1	2013-14		
2	2014-15		
3	2015-16		
	Total	Rs.	Lakhs
		or	
4	2014-15		
5	2015-16		
6	2016-17		
	Total	Rs.	Lakhs
A 374	erage furnover ner annual	Re	Lakhe

Date:	Siganture of Auditor/
	Chartered Accountant
Seal:	(Name in Capital)

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

Name of the Laboratory:				
Address:				
Types of Samples Analysed (2013-14)	No. of Samples Analysed during 4, 2014-15, 2015-2016 or 2014-15, 2015-2016, 2016-2017)			
01. Surgicals (Specify item nar	nes)			
02. Sutures (Specify types)				
03. Implants				
04. Devices				
05. Drugs & Medicines				
06. Others (Specify)				
	Signature:			
	Date:			
	Name of the Lab:			
	Office Seal :			

PERSONNEL IN QC DEPARTM ENT

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

Signature:
Date:
Name of the Lab

Office Seal:

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

S.No.	Name of the Equipment Instruments / Apparatus	Make & Description	Date of Installation	Date of last Validation	Approved for testing of drugs from State licensing Authority since
				Signature:	
				Name of th	ne Lab:
				Date:	
				Official Sea	al:

FACILITIES IN THE MICROBIOLOGICAL SECTION

I.	LIST	OF	STOCK	CULTURES	AVAIL	ABLE

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)

LISTOF REFERENCES SAMPLES ALONG WITH THEIR DATE OF PROCUREMET AND QUANTITIES, If required for any item.

Signature:
Name of the Lab
Date:
Official Seal:

Affidavit (On Non Judicial Stamp of Rs.100/-)

ANNEXURE – V Ref. Clause No: 3(k)

(Affidavit Page-1)

DECLARATION FORM

1.	I (Name of the	Bidder) S/O	, Age	, resident of	, am
	proprietor /Partne	er/Director having o	ur office at		
	and the		drug	testing	laboratory
		the conditions of bio			
	Ltd., Jaipur, for	the bids floated for	or empanelme	ent of approved	drugs testing
		analysis of surgical & .2019) and shall abid		<u> </u>	
2.	. •	that I possess valid a	<u> </u>		
		hich Price Bid have	* *	•	0
		orm 37 have been of		•	
	•	rity where ever applic		C	
3.	· ·	1 to test drugs/surgic		nave been obtained	d on Form 37
	bearing No	which is val	lid/renewed up	o to	•
4.	That the Bidden	firm is a proprie	torship/Partne	ership/Pvt. Ltd./Lt	td. firm and
	following are the	other partners/direct	ors:-		
S.N	No. Nam	ne of Partner/Director	Age		& Permanent Idress
5.	That our laborate	ory/Firm/Company do	oes not stand	blacklisted /debarr	ed or banned
	on any ground e	ther by Bid Inviting	Authority or	Govt. of Rajastha	n on the date
	of bid submission	1.			
,	Our laboratory/Ein	m/Company also do	as not stand h	Joolsligtad dabarra	ad ar hannad
	•	m/Company also do- rong reporting of te			
	•	cuments or false inf		•	
	· ·	its central drug p			
	•	oly of drugs/medicine		igencies, on the	uaic of oid
вu	omission for supp	iy of drugs/medicine	o m maia.		

- 6. That i/we have carefully read all the conditions of bid in ref. No. F.02(45)/RMSCL/Proc/LABEMPANELMENT(S&S)/NIB-7/2017/265 Dated:26.07.2017 for the empanelment of analytical testing laboratories for the test and analysis of Surgical & Sutures for the year 2017-2019 (Ending on 30.09.2019) for Rajasthan Medical Services Corporation Limited 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.:-			
9.	E-mail address :-			
	(Affic	davit – Page2)		

10. Bank detail for e -Banking:-	
Name of account holder	
Full name of Bank with Branch	
A/c no. with full digits	
IFSC code	
	(Deponent)
	, ,
	Signature:
	Date:
	Name of the Lab:
	Office Seal:
<u>Verification</u>	
I	Prop./
Partner/ Director of Lab M/s Ad	dress
Affirm on oath that the contents/information from para 1 to	o 10 as mentioned above, are
true & correct to the best of my knowledge and nothing is h	idden. I also declare on oath,
that if any information furnished by me as above is for	und wrong, false, forged or
fabricated; the Corporation will be at liberty to cancel the b	oid and forfeiting the earnest
money deposit and or performance security, for which I sh	all be solely responsible and
the laboratory / firm may be Debarred/Banned/ prosecuted for	or the same
(NI	
(Nam	e of Deponent & Signature)
ATTESTED BY NOTARY PUBLIC	
	(Affidavit Page 3)

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 Start testing of Surgicals & : Sutures		
5.	Approval No. & Date	:	
6.	Approval Issued by	:	
7.	Valid up to	:	
8. 9.	(ii) Scope of Accreditation	:	
10.	(iii) Its validity. Name of the authorized signatory of Lab	:	
11.	Specimen Signature of the authorized Signatory of Lab.	:	
12.	Names & Specimen Signatures of the Approved technical Staff who are authorized to sign the test reports	:	
	(1) (Name)		(Specimen Signature)
	(2) (Name)		(Specimen Signature)

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	Test Proposed to be carried out	Remarks
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
4.	R-4	Absorbable Surgical Suture (Sterile Catgut), BP/USP Needled Suture Chromic (I/2 Cir RB Needle 30mm Length 76 cm)	1/0	12 Foils	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
8.	R-8	Absorbable Surgical Suture (Sterile Catgut), Needled Suture Chromic (3/8 Cir RCutting Needle 26mm, Length 76 cm)	3/0	12 Foils	As per Annexure VIII	
9.	R-9	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	3/0	12 Foils	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
15.	R-15	Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polyglycolic Acid / Poly(Glycolide-co-L-lactide)	4/0	12 Foils	As per Annexure VIII	

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Test Proposed to be carried out	Remarks
		(1/2 Cir RB Needle 20mm length 70 cm)				
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Test Proposed to be carried out	Remarks
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
42.	R-42	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (3/8 Cir	6/0	12 Foils	As per Annexure VIII	

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Test Proposed to be carried out	Remarks
		RB 13mm Needle, Length 90 cm Double Arm				
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
46.	R-46	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir Reverse Cutting, 45 mm Needle length 100 cm)	1	12 Foils	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
52.	R-52	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BRAIDED COATED POLYSTER, GREEN/WHITE or BLUE/WHITE Polybutylate / Silicon Coated Polyster Braided green/ blue (1/2 Cir Tapercut, 17 mm Double Needle, length 75 cm)	4/0	12 Foils	As per Annexure VIII	
53.	R-53	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BRAIDED COATED POLYSTER, GREEN/WHITE or BLUE/WHITE Polybutylate / Silicon Coated Polyster Braided White (1/2 Cir Tapercut ,17 mm Double Needle, length 90 cm)	2/0	12 Foils	As per Annexure VIII	
54.	R-54	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BRAIDED COATED POLYSTER, GREEN/WHITE or BLUE/WHITE Polybutylate / Silicon Coated Polyster	2/0	12 Foils	As per Annexure VIII	

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Test Proposed to be carried out	Remarks
		Braided Green / Blue (1/2 Cir Tapercut ,17 mm Double Needle, length 90 cm)				
55.	R-55	Non absorbable surgical suture sterilized surgical needled suture Polybutylate / Silicon Coated with Polyster Braided (Green / Blue) 1/2 Circle Taper cut, 17mm Double armed Needle, Suture Length of 90cm with pledgets Size 6 X 3 X 1.5mm	2/0	6 Foils	As per Annexure VIII	
56.	R-56	Non absorbable surgical suture sterilized surgical needled suture Polybutylate / Silicon Coated with Polyster Braided (Green / Blue) *with 1/2 Circle Taper cut, 25mm Double armed Needle, Suture Length of 90cm with pledgets Size 6 X 3 X 1.5mm	2/0	6 Foils	As per Annexure VIII	
57.	R-57	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BRAIDED COATED POLYSTER, GREEN/WHITE or BLUE/WHITE Coated Polyster Braided (Green / Blue) with 1/2 Circle Tapercut Double Needle 25mm, Suture Length 90 cm	3/0	12 Foils	As per Annexure VIII	
58.	R-61	ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYGLECAPRONE / Polyglyconate, MONOFILAMENT SUTURES (1/2 Circle Oval RB Needle 26mm Needle, Suture Length of 70cm)	Size 2/0	12 Foils	As per Annexure VIII	
59.	R-62	ABSORBABLE SURGICAL SUTURES POLYGLECAPRONE / Polyglyconate, MONOFILAMENT SUTURES (I/2 Circle Oval RB Contrast Needle 26mm, suture length 70cm)	3/0	12 Foils	As per Annexure VIII	
60.	R-63	ABSORBABLE SURGICAL SUTURES Monofilament sutures Polyglecaprone /Polyglyconate (I/2 Circle Cutting 16mm Needle,suture length 70cm)	4/0	12 Foils	As per Annexure VIII	
61.	R-64	ABSORBABLE SURGICAL SUTURES POLYGLECAPRONE / Polyglyconate, MONOFILAMENT SUTURES (3/8 Circle Cutting 24-26mm Needle, Suture Length of 70-90cm)	3/0	12 Foils	As per Annexure VIII	
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	As per Annexure VIII	
63.	R-66	ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILA MENT POLYDIOXANONE Violet (1/2 Circle RB 31mm Needle, Length 70cm)	2/0	36 Foils	As per Annexure VIII	
64.	R-67	ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYDIOXANONE Violet (1/2 Circle RB 30mm Needle, Length 70cm)	1/0	12 Foils	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	

S.No.	Code No.	Name of approved item (s) with specification	Size	Packing Unit	Test Proposed to be carried out	Remarks
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
72.	R-75	NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYAMIDE MONOFILAMENT BLACK (NYLON) (3/8 Cutting spatulated Edge Needle, Double arm Needle 6 mm, Suture length 30-42 cm	10/0	12 Foils	As per Annexure VIII	
73.	R-76	Absorbable Surgical Suture (Sterile Catgut), Needled Suture Chromic (3/8 Cir RCutting Needle 16mm, Length 76 cm)	5/0	12 Foils	As per Annexure VIII	
74.	R-77	Absorbable Surgical Suture (Sterile Catgut), Needled Suture Chromic (3/8 Cir Cutting Needle 8mm, Length 35 cm)	6/0	12 Foils	As per Annexure VIII	
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	As per Annexure VIII	
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	As per Annexure VIII	
77.	R-80	Absorbable Surgical Suture (Sterile Catgut), Needled Suture Chromic (3/8 Cir RCutting Needle 19mm Length 76 cm)	4/0	12 Foils	As per Annexure VIII	

SURGICAL LIST

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Test Proposed to be carried out	Remarks
1.	S-1	Absorbable Gelatin Sponge IP 66, Size 80(+-10) mm x 50 mm x 10 mm should be sterlized.	Piece	As per Annexure VIII	
2.	S-2	Absorbent Cotton Wool IP 500 gm	Packet	As per Annexure VIII	
3.	S-3	Asepto Syringe with Transparent Bulb Sterile, 60 ml	Piece	As per Annexure VIII	
4.	S-4	 Blood Administration Set / Blood Transfusion Set Sharp and easy piercing spike suitable for blood bags and standard blood containers Transparent cylindrical drip chamber with filter. Filter size should be 200+20 micro meter. 150 cm long smooth kink resistant tubing Efficient roller clamp to control and adjust the transfusion rate Should conform to IS 9824(Part 3):1996 	Unit	As per Annexure VIII	
5.	S-5(a)	Disposable Sterile Surgical Rubber Gloves Size 6 ½ Inches • Made of natural rubber Latex, powdered, without tear, properly folded in a paper • Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less • Tensile strength as per EN 455-2 • Powder should be non-allergenic • should Conform to IS 13422 • ISI marked / CE certified / FDA approved	Pair	As per Annexure VIII	
6.	S- 5(b)	 Disposable Sterile Surgical Rubber Gloves Size 6 ½ Inches Made of natural rubber Latex, powder free (Polymer /Silicon Coated), without tear, properly folded in a paper Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less Tensile strength as per EN 455-2 should Conform to 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	As per Annexure VIII	
7.	S-6(a)	Disposable Sterile Surgical Rubber Gloves Size 7 Inches • Made of natural rubber Latex, powdered,, without tear, properly folded in a paper • Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less • Tensile strength as per EN 455-2 • Powder should be non-allergenic • should Conform to IS 13422 • ISI marked / CE certified / FDA approved	Pair	As per Annexure VIII	
8.	S- 6(b)	 Disposable Sterile Surgical Rubber Gloves Size 7 Inches Made of natural rubber Latex, powder free (Polymer /Silicon Coated), without tear, properly folded in a paper Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less Tensile strength as per EN 455-2 	Pair	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification	Packing Unit	Test Proposed to be carried out	Remarks
		• should Conform to IS 13422 ISI marked / CE certified / FDA approved (CE Certification / FDA Approval for item is mandatory for importer firms, that cannot avail IS Standards)			
9.	S-7(a)	 Disposable Sterile Surgical Rubber Gloves Size 7½ Inches Made of natural rubber Latex, powdered, without tear, properly folded in a paper Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less Tensile strength as per EN 455-2 Powder should be non-allergenic should Conform to IS 13422 ISI marked / CE certified / FDA approved 	Pair	As per Annexure VIII	
10.	S- 7(b)	 Disposable Sterile Surgical Rubber Gloves Size 7 ½ Inches Made of natural rubber Latex, powder free (Polymer /Silicon Coated), without tear, properly folded in a paper Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less Tensile strength as per EN 455-2 should Conform to 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	As per Annexure VIII	
11.	S-8(a)	 Suction Catheter, Sterile. Size: FG 5 (For use in respiratory tract) Soft, kink resistant tubing Rounded open tip with lateral eye Colour coded universal funnel connector for safe connection to standard suction equipment Length 50 cm (min.) Should conform to ISO 8836:2014 	Each Piece	As per Annexure VIII	
12.	S- 8(b)	 Suction Catheter, Sterile. Size: FG 6 (For use in respiratory tract) Soft, kink resistant tubing Rounded open tip with lateral eye Colour coded universal funnel connector for safe connection to standard suction equipment Length 50 cm (min.) Should conform to ISO 8836:2014 	Each piece	As per Annexure VIII	
13.	S-8(c)	Suction Catheter, Sterile. Size: FG 8 (For use in respiratory tract) Soft, kink resistant tubing Rounded open tip with lateral eye Colour coded universal funnel connector for safe connection to standard suction equipment Length 50 cm (min.) Should conform to ISO 8836:2014	Each piece	As per Annexure VIII	
14.	S- 8(d)	Suction Catheter, Sterile. Size: FG 10 (For use in respiratory tract) Soft, kink resistant tubing Rounded open tip with lateral eye Colour coded universal funnel connector for safe connection to standard suction equipment Length 50 cm (min.) Should conform to ISO 8836:2014	Each piece	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Test Proposed to be carried out	Remarks
15.	S-8(e)	Suction Catheter, Sterile. Size: FG 12 (For use in respiratory tract) Soft, kink resistant tubing Rounded open tip with lateral eye Colour coded universal funnel connector for safe connection to standard suction equipment Length 50 cm (min.) Should conform to ISO 8836:2014	Each piece	As per Annexure VIII	
16.	S-8(f)	Suction Catheter, Sterile. Size: FG 14 (For use in respiratory tract) Soft, kink resistant tubing Rounded open tip with lateral eye Colour coded universal funnel connector for safe connection to standard suction equipment Length 50 cm (min.) Should conform to ISO 8836:2014	Each piece	As per Annexure VIII	
17.	S- 8(g)	Suction Catheter, Sterile. Size: FG 16 (For use in respiratory tract) Soft, kink resistant tubing Rounded open tip with lateral eye Colour coded universal funnel connector for safe connection to standard suction equipment Length 50 cm (min.) Should conform to ISO 8836:2014	Each piece	As per Annexure VIII	
18.	S- 8(h)	Suction Catheter, Sterile. Size: FG 18 (For use in respiratory tract) Soft, kink resistant tubing Rounded open tip with lateral eye Colour coded universal funnel connector for safe connection to standard suction equipment Length 50 cm (min.) Should conform to ISO 8836:2014	Each piece	As per Annexure VIII	
19.	S-8(i)	Suction Catheter, Sterile. Size: FG 20 (For use in respiratory tract) Soft, kink resistant tubing Rounded open tip with lateral eye Colour coded universal funnel connector for safe connection to standard suction equipment Length 50 cm (min.) Should conform to ISO 8836:2014	Each Piece	As per Annexure VIII	
20.	S-8(j)	Suction Catheter, Sterile. Size: FG 22 (For use in respiratory tract) Soft, kink resistant tubing Rounded open tip with lateral eye Colour coded universal funnel connector for safe connection to standard suction equipment Length 50 cm (min.) Should conform to ISO 8836:2014	Each Piece	As per Annexure VIII	
21.	S-9(a)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size 8 FG Made of Silicone elastomer bonded with Latex Should have hard plastic valve Smooth distal end with smooth eyes for atraumatic intubation Symmetrical foley balloon	Each Piece	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification	Packing Unit	Test Proposed to be carried out	Remarks
		 Balloon capacity 3-5 ml Should conform to 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 			
22.	S- 9(b)	 Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size10 FG Made of Silicone elastomer bonded with Latex Should have hard plastic valve Smooth distal end with smooth eyes for atraumatic intubation Symmetrical foley balloon Balloon capacity 3-5 ml Should conform to 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	As per Annexure VIII	
23.	S-9(c)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size16 FG Made of Silicone elastomer bonded with Latex Should have hard plastic valve Smooth distal end with smooth eyes for atraumatic intubation Symmetrical foley balloon Balloon capacity 30 ml Should conform to 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	As per Annexure VIII	
24.	S- 9(d)	 Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size18 FG Made of Silicone elastomer bonded with Latex Should have hard plastic valve Smooth distal end with smooth eyes for atraumatic intubation Symmetrical foley balloon Balloon capacity 30±1 ml Should conform to 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	As per Annexure VIII	
25.	S-9(e)	Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size20 FG • Made of Silicone elastomer bonded with Latex • Should have hard plastic valve • Smooth distal end with smooth eyes for atraumatic intubation • Symmetrical foley balloon • Balloon capacity 30 ± 1 ml	Each piece	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification	Packing Unit	Test Proposed to be carried out	Remarks
		 Should conform to 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 			
26.	S-9(f)	 Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size22 FG Made of Silicone elastomer bonded with Latex Should have hard plastic valve Smooth distal end with smooth eyes for atraumatic intubation Symmetrical foley balloon Balloon capacity 30 ± 1 ml Should conform to 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	As per Annexure VIII	
27.	S- 9(g)	 Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size 24 FG Made of Silicone elastomer bonded with Latex Should have hard plastic valve Smooth distal end with smooth eyes for atraumatic intubation Symmetrical foley balloon Balloon capacity 30 ± 1 ml Should conform to 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	As per Annexure VIII	
28.	S-10 (a)	 Infant Feeding Tube Size:10FG length 50 cm (min.) Two lateral eyes at distal end Soft, kink resistant non-toxic PVC tubing, non irritant to delicate mucosa With female flexible mount with in-built closure Radio opaque line Sterile 	Each Piece	As per Annexure VIII	
29.	S-10 (b)	 Infant Feeding Tube Size:8FG, length 50 cm (min.) Two lateral eyes at distal end Soft, kink resistant non-toxic PVC tubing, non irritant to delicate mucosa With female flexible mount with in-built closure Radio opaque line Sterile 	Each Piece	As per Annexure VIII	
30.	S-10 (c)	Infant Feeding Tube Size:5FG length 50 cm (min.) Two lateral eyes at distal end Soft, kink resistant non-toxic PVC tubing, non irritant to delicate mucosa With female flexible mount with in-built closure Radio opaque line Sterile	Each Piece	As per Annexure VIII	

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

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Test Proposed to be carried out	Remarks
40.	S-16	Mucus Extractor Sterile Clear transparent container Antibacterial filter Soft, kink resistant PVC tubing Tube Size 10 FG; Length 40 cm (min.) Capacity 25 ml	Unit	As per Annexure VIII	
41.	S- 17(a)	Nasal Oxygen Cannula (Set), Twin Bore (accessory for compressed air breathing) All Sizes (Adult) Soft and kink resistant PVC tubing Multichannel/star lumen to preventing accidental kinking Twin bores should ensure equal volume of oxygen to both air passages Connector for easy connection to the oxygen source Tube length 200 cm	Each Piece	As per Annexure VIII	
42.	S- 17(b)	Nasal Oxygen Cannula (Set), Twin Bore (accessory for compressed air breathing) All Sizes (Pediatrics) Soft and kink resistant PVC tubing Multichannel/star lumen to preventing accidental kinking Twin bores should ensure equal volume of oxygen to both air passages Connector for easy connection to the oxygen source Tube length 200 cm	Each Piece	As per Annexure VIII	
43.	S-18	Paper Adhesive Plaster 1" X 9.0 mts (with cutter) Non woven adhesive tape,hypoallergic,should have some stretch bonding	Unit	As per Annexure VIII	
44.	S-19	Paper Adhesive Plaster 2" X 9.0 mts (with cutter) Non woven adhesive tape hypoallergic, should have some stretch bonding	Unit	As per Annexure VIII	
45.	S-20	Paper Adhesive Plaster 3" X 9.0 mts (with cutter) Non woven adhesive tape hypoallergic, should have some stretch bonding	Unit	As per Annexure VIII	
46.	S-21	Plaster of Paris Bandages 15cm X 2.7mts / Roll Should conform to Schedule F(II) of Drug and Cosmetic Act 1940	Unit	As per Annexure VIII	
47.	S-22	Plaster of Paris Bandages 10cm X 2.7mts / Roll Should conform to Schedule F(II) of Drug and Cosmetic Act 1940	Unit	As per Annexure VIII	
48.	S-23 (a)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 10 Soft, kink resistant PVC tubing for atraumatic intubation Closed distal end should be coned with radio opaque material for accurate intubation Four lateral eyes for greater efficiency Radio opaque line Marking at 50, 60, 70 cm from tip Colour coded funnel With luer connector / closure Length 105 cm	Each Piece	As per Annexure VIII	
49.	S-23 (b)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 12 Soft, kink resistant PVC tubing for atraumatic intubation Closed distal end should be coned with radio opaque material for accurate intubation Four lateral eyes for greater efficiency	Each Piece	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Test Proposed to be carried out	Remarks
		 Radio opaque line Marking at 50, 60, 70 cm from tip Colour coded funnel With luer connector / closure 			
50.	S-24 (a)	 Length 105 cm Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 14 Soft, kink resistant PVC tubing for atraumatic intubation Closed distal end should be coned with radio opaque material for accurate intubation Four lateral eyes for greater efficiency Radio opaque line Marking at 50, 60, 70 cm from tip Colour coded funnel With luer connector / closure Length 105 cm 	Each Piece	As per Annexure VIII	
51.	S-24 (b)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 16 Soft, kink resistant PVC tubing for atraumatic intubation Closed distal end should be coned with radio opaque material for accurate intubation Four lateral eyes for greater efficiency Radio opaque line Marking at 50, 60, 70 cm from tip Colour coded funnel With luer connector / closure Length 105 cm	Each Piece	As per Annexure VIII	
52.	S-24 (c)	Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 18 • Soft, kink resistant PVC tubing for atraumatic intubation • Closed distal end should be coned with radio opaque material for accurate intubation • Four lateral eyes for greater efficiency • Radio opaque line • Marking at 50, 60, 70 cm from tip • Colour coded funnel • With luer connector / closure • Length 105 cm	Each Piece	As per Annexure VIII	
53.	S- 25(a)	Scalp Vein Set (Disposable): Size 18G Butterfly shaped wings for easy handling and attachment with skin. Colour coded Needle should be bevelled, siliconised and should ensure atraumatic cannulation Female luer fitting at one end Soft, kink resistant, non-toxic, non irritant tube Sterile	Each Piece	As per Annexure VIII	
54.	S- 25(b)	Scalp Vein Set (Disposable): Size 20G Butterfly shaped wings for easy handling and attachment with skin. Colour coded Needle should be bevelled, siliconised and should ensure atraumatic cannulation Female luer fitting at one end Soft, kink resistant, non-toxic, non irritant tube	Each Piece	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification • Sterile	Packing Unit	Test Proposed to be carried out	Remarks
		Stelle			
55.	S- 25(c)	 Scalp Vein Set (Disposable): Size 22G Butterfly shaped wings for easy handling and attachment with skin. Colour coded Needle should be bevelled, siliconised and should ensure atraumatic cannulation Female luer fitting at one end Soft, kink resistant, non-toxic, non irritant tube 	Each Piece	As per Annexure VIII	
56.	S- 25(d)	 Sterile Scalp Vein Set (Disposable): Size 24G Butterfly shaped wings for easy handling and attachment with skin. Colour coded Needle should be bevelled, siliconised and should ensure atraumatic cannulation Female luer fitting at one end Soft, kink resistant, non-toxic, non irritant tube Sterile 	Each Piece	As per Annexure VIII	
57.	S-26	Sterile Hypodermic Syringe with Needle attached, 24G, Single Use - 2 ml Clear transparent chamber Prominent graduation Inert material gasket at the piston to minimise friction during movement & prevent leakage and back flow Sharp needle ensuring minimum trauma during penetration 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.	Unit	As per Annexure VIII	
58.	S-27	Sterile Hypodermic Syringe with Needle attached, 24G, Single Use - 5 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.	Unit	As per Annexure VIII	
59.	S-28	Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 10 ml Clear transparent chamber Prominent graduation Inert material gasket at the piston to minimise friction during movement & prevent leakage and back flow Sharp needle ensuring minimum trauma during penetration 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	Unit	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification equivalent should be written on Unit Container.	Packing Unit	Test Proposed to be carried out	Remarks
		-			
60.	S-29	Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 20 ml Clear transparent chamber Prominent graduation Inert material gasket at the piston to minimise friction during movement & prevent leakage and back flow Sharp needle ensuring minimum trauma during penetration Shall conform to IS 12050 Packing: Needle should be attached with the syringe and	Unit	As per Annexure VIII	
		packed in unit ribbon pack The words "DESTROY AFTER SINGLE USE" or			
		equi valent should be written on Unit Container.			
61.	S-30 (a)	 Surgical Blade Sterile, Size 11 Single peel pack in metal foil The tip of the blade shall be well defined, central and sharp. There shall be no waviness, jags, feathers, nicks, or other defects on the cutting edge. The surfaces of the blade shall be smooth and free from tool marks and any sign of corrosion. Should conform to IS 3319 	100Blades/ Packet	As per Annexure VIII	
62.	S-30	Surgical Blade Sterile, Size 15	100Blades/	As per	
	(b)	 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 	Packet	Annexure VIII	
63.	S-30 (c)	 Surgical Blade Sterile, Size 22 Single peel pack in metal foil The tip of the blade shall be well defined, central and sharp. There shall be no waviness, jags, feathers, nicks, or other defects on the cutting edge. The surfaces of the blade shall be smooth and free from tool marks and any sign of corrosion. Should conform to IS 3319 	100Blades/ Packet	As per Annexure VIII	
64.	S-31	Suture Needles Curved 1/2 Circle Round Body Assorted Size 11- 15 It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. Should conform to IS-9165	6 Nos./Pkt.	As per Annexure VIII	
65.	S-32	 Suture Needles Curved 1/2 Circle Round Body Assorted Size 1-5 It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. Should conform to IS-9165 	6 Nos./Pkt.	As per Annexure VIII	
66.	S-33	 Suture Needles Curved 1/2 Circle Round Body Assorted Size 16-20 It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. Should conform to IS-9165 	6 Nos./Pkt.	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Test Proposed to be carried out	Remarks
67.	S-34	 Suture Needles Curved 1/2 Circle Round Body Assorted Size 6-10 It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. Should conform to IS-9165 	6 Nos./Pkt.	As per Annexure VIII	
68.	S-35	 Suture Needles Curved And Cutting 1/2 Circle Cutting Size 6-10 It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. Should conform to IS-9165 	6 Nos. /Pkt.	As per Annexure VIII	
69.	S-36	 Suture Needles Curved And Cutting 1/2 Circle Size 11-15 It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. Should conform to IS-9165 	6 Nos./Pkt.	As per Annexure VIII	
70.	S-37	 Suture Needles Curved And Cutting 1/2 Circle Size 16-20 It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. Should conform to IS-9165 	6 Nos./Pkt.	As per Annexure VIII	
71.	S-38	 Suture Needles Curved And Cutting Size 1-5 It should be mentioned whether needle is Pointed or blunt with type of its point. Type of eye of the needle should be mentioned. Should conform to IS-9165 	6 Nos./Pkt.	As per Annexure VIII	
72.	S- 39(a)	 Sterile Disposable Spinal Needle for Single Use 22G x 3 ½ inch Clear / transparent hub Sharp tip which should ensure minimal puncture trauma 	Each piece	As per Annexure VIII	
73.	S- 39(b)	 Sterile Disposable Spinal Needle for Single Use 25G x 3 ½ inch Clear / transparent hub Sharp tip which should ensure minimal puncture trauma 	Each piece	As per Annexure VIII	
74.	S-40	Urine Collecting Bag, Disposable 2000 ml Transparent sheet Kink resistant flexible tubing not less than 90 cm in length should have non-return valve Top drainage outlet Graduated bag Moulded handle for easy handling	Unit	As per Annexure VIII	
75.	S-41 (a)	 Double J Stent, Sterile, Both Ends Open - size 4F, length 16 cm Radio opaque Should be of inert material, non-irritant to tissue 	Each piece	As per Annexure VIII	
76.	S-41 (b)	 Double J Stent, Sterile, Both Ends Open, size 5F, length 20 cm Radio opaque Should be of inert material, non-irritant to tissue 	Each piece	As per Annexure VIII	
77.	S-42 (a)	 Double J Stent, Sterile, One End Closed - size 4F, length 16 cm Radio opaque Should be of inert material, non-irritant to tissue 	Each piece	As per Annexure VIII	
78.	S-42 (b)	 Double J Stent, Sterile, One End Closed, size 5F, length 20 cm Radio opaque Should be of inert material, non-irritant to tissue 	Each piece	As per Annexure VIII	
79.	S- 43(a)	Endotracheal Tube, Plain - Size 2.5mm Transparent	Each piece	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification	Packing Unit	Test Proposed to be carried out	Remarks
		 Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nasal and oral intubation Single use, sterile 			
80.	S- 43(b)	 Endotracheal Tube, Plain - Size 3mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nas al and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	
81.	S- 43(c)	 Endotracheal Tube, Plain - Size 3.5mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nas al and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	
82.	S- 43(d)	 Endotracheal Tube, Plain - Size 4mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nas al and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	
83.	S- 43(e)	 Endotracheal Tube, Plain - Size 4.5mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nasal and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	
84.	S- 43(f)	 Endotracheal Tube, Plain - Size 5mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nas al and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	
85.	S- 43(g)	 Endotracheal Tube, Plain - Size 5.5mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nasal and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	
86.	S-43 (h)	Endotracheal Tube, Plain with radio-opaque line, Sterile, Single Use - Size 6mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nas al and oral intubation Single use, sterile	Each piece	As per Annexure VIII	
87.	S- 43(i)	 Endotracheal Tube, Plain - Size 6.5mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nas al and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification	Packing Unit	Test Proposed to be carried out	Remarks
88.	S- 43(j)	 Endotracheal Tube, Plain - Size 7mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nas al and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	
89.	S- 43(k)	 Endotracheal Tube, Plain - Size 7.5mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nas al and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	
90.	S- 43(1)	 Endotracheal Tube, Plain - Size 8mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nas al and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	
91.	S- 43(m)	 Endotracheal Tube, Plain - Size 8.5mm Transparent Standard 15 mm connector at proximal end Radio-opaque line throughout the length Tip suitable for nas al and oral intubation Single use, sterile 	Each piece	As per Annexure VIII	
92.	S- 44(a)	 Endotracheal Tube, Cuffed - Size 4mm Soft cuff towards the distal end Kink resistant inflation tube Murphy eye at distal end with polished smoothness Radio-opaque line Standard 15 mm connector Sterile, single use Curved shaped blister pack – suiting the shape of product 	Each piece	As per Annexure VIII	
93.	S- 44(b)	 Endotracheal Tube, Cuff - Size 4.5mm Soft cuff towards the distal end Kink resistant inflation tube Murphy eye at distal end with polished smoothness Radio-opaque line Standard 15 mm connector Sterile, single use Curved shaped blister pack – suiting the shape of product 	Each piece	As per Annexure VIII	
94.	S-44 (c)	 Endotracheal Tube, Cuff - Size 5mm Soft cuff towards the distal end Kink resistant inflation tube Murphy eye at distal end with polished smoothness Radio-opaque line Standard 15 mm connector Sterile, single use Curved shaped blister pack – suiting the shape of product 	Each Piece	As per Annexure VIII	
95.	S-44 (d)	 Endotracheal Tube, Cuff - Size 6mm Soft cuff towards the distal end Kink resistant inflation tube Murphy eye at distal end with polished smoothness Radio-opaque line 	Each Piece	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification Standard 15 mm connector Sterile, single use	Packing Unit	Test Proposed to be carried out	Remarks
96.	S-44	Curved shaped blister pack – suiting the shape of product Endotracheal Tube, Cuff - Size 6.5mm	Each Piece	As man	
90.	(e)	 Soft cuff towards the distal end Kink resistant inflation tube Murphy eye at distal end with polished smoothness Radio-opaque line Standard 15 mm connector 	Each Piece	As per Annexure VIII	
		• Sterile, single use			
		Curved shaped blister pack – suiting the shape of product			
97.	S- 44(f)	 Endotracheal Tube, Cuff - Size 7mm Soft cuff towards the distal end Kink resistant inflation tube Murphy eye at distal end with polished smoothness Radio-opaque line Standard 15 mm connector Sterile, single use Curved shaped blister pack – suiting the shape of product 	Each piece	As per Annexure VIII	
98.	S-	Endotracheal Tube, Cuff - Size 7.5	Each piece	As per	
	44(g)	 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 		Annexure VIII	
99.	S-	Endotracheal Tube, Cuff - Size 8	Each piece	As per	
	44(h)	 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 		Annexure VIII	
100.	S- 44(i)	 Endotracheal Tube, Cuff - Size 8.5 Soft cuff towards the distal end Kink resistant inflation tube Murphy eye at distal end with polished smoothness Radio-opaque line Standard 15 mm connector Sterile, single use Curved shaped blister pack – suiting the shape of product 	Each piece	As per Annexure VIII	
101.	S- 44(j)	 Endotracheal Tube, Cuff - Size 9 Soft cuff towards the distal end Kink resistant inflation tube Murphy eye at distal end with polished smoothness Radio-opaque line Standard 15 mm connector Sterile, single use Curved shaped blister pack – suiting the shape of product 	Each piece	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification	Packing Unit	Test Proposed to be carried out	Remarks
102.	S-45	Tracheostomy Tube (PVC), Plain, Sterile, Single Use - All Sizes Soft flexible flange at for easy fixation 15 mm connector at terminal end which can be rotated in 360 degree direction Non-irritant Radio-opaque line	Each Piece	As per Annexure VIII	
103.	S-46	Tracheostomy Tube (PVC), Cuffed, Sterile, Single Use - All Sizes Soft flexible flange at for easy fixation Soft me connector at terminal end which can be rotated in 360 degree direction Non-irritant Radio-opaque line Balloon with non return valve	Each Piece	As per Annexure VIII	
104.	S- 47(a)	Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag (2000 ml) (size 24) Graduated Bag Should have well fitting cap Soft drainage catheter 50 cm long, with radio opaque line Rounded open distal end with smooth atraumatic eyes in catheter Catheter with markings at 2 cm interval	Each Piece	As per Annexure VIII	
105.	S- 47(b)	Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag (2000 ml) (size 28) • Graduated Bag • Should have well fitting cap • Soft drainage catheter 50 cm long, with radio opaque line • Rounded open distal end with smooth atraumatic eyes in catheter	Each Piece	As per Annexure VIII	
106.	S- 47(c)	S- Abdominal Drain Kit, Sterile, Having drainage catheter and		As per Annexure VIII	
107.	S-48	Corrugated Drainage Sheet, Sterile, Multichannel, with radio opaque line, Single Use - All sizes	Each Piece	As per Annexure VIII	
108.	S-73	Polypropylene Nonabsorbable Synthetic Surgical Mesh 7.5 cmX 15 cm soft to feel fast edges, slightly stretchbonding.	Piece	As per Annexure VIII	
109.	S-74	Polypropylene Nonabsorbable Synthetic Surgical Mesh 15 cmX 15 cm soft to feel fast edges, slightly stretchbonding.	Piece	As per Annexure VIII	
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	As per Annexure VIII	
111.	S-80	Bone Wax Sterilised	2 gm/ Packet	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Test Proposed to be carried out	Remarks
112.	S-81	Temporary Cardiac Pacing Wire (Electrode) Sterile ½ Cir, Tapercut, 26 mm; straight cutting 60 mm, breakaway	Sachet	As per Annexure VIII	
113.		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 Should conform to IS 3759. Skin Grafting Knife Handle (Watson modification of Humby's Knife) Stainless Steel, CE certified, in which the blade specified in (a) above should fit snugly. Should conform to 7980-1976.	One Pack Each	As per Annexure VIII	
114.	S- 84(a)	K Wire, length 375 mm; 1mm Length of wire should be mentioned with specification. Should conform to IS 8261	Each Unit	As per Annexure VIII	
115.	S- 84(b)	 K Wire, length 375 mm; 1.6mm Length of wire should be mentioned with specification. Should conform to IS 8261 	Each Unit	As per Annexure VIII	
116.	S- 84(c)	K Wire, length 375 mm; size 1.8mm • Length of wire should be mentioned with specification. Should conform to IS 8261	Each Unit	As per Annexure VIII	
117.	S-85	 Face Mask, Disposable Should be manufactured from non woven poly prop fabric Should be 3 ply construction Should have high bacterial filtration efficiency Should be heat sealed to keep 3 layers together Standard size 17.5 x9 cm Color green/blue There should be a string each at all four corners, length of string should be 40cm Nose clip should be there No elastic band. 	Piece	As per Annexure VIII	
118.	S-86 (a)	 Surgical Cap, Disposable (For Surgeons) Should be manufactured from non woven fabric. Strip for tying the cap stitched on the back for proper grip on the forhead. Green colour Ultrasonically stitched Air permeable/breathable Should retain skin and hair particle. Strip for tying the cap 	Piece	As per Annexure VIII	
119.	S-86 (b)	Surgical Cap, Disposable (For Nurses) Should be manufactured from non woven fabric Blue / Green colour Round upon wearing, with elastic Air permeable / breathable Should retain skin and hair particles	Piece	As per Annexure VIII	
120.	S- 87(a)	Foldable Intra Ocular lense with injector (Size + 11 D to +17.5 D) Size:6mm optics. 12-13mm total diameter 1. Made of foldable Acrylic (Hydrophobic) material 2. Bi-Convex single piece IOL with aspheric optics 3. Size:6mm optics. 12-13mm total diameter.	Each piece	As per Annexure VIII	

		Unit	Proposed to be carried out	
	4. Modified C loop haptic/plate haptics (5. IOL should have UV blocking capability 6. IOL should have 360° square edge			
	7. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision 8. Diopters - + 11 D to +17.5 D at 0.5 D step. 9. Supplying unit should be ISO accredited and IOL should be			
-	CE/US FDA certified.			
S- 87(b)	Foldable Intra Ocular lense with injector (Size + 18 D to + 24 D) Size:6mm optics. 12-13mm total diameter 1. Made of foldable Acrylic (Hydrophobic) material 2. Bi-Convex single piece IOL with aspheric optics 3. Size:6mm optics. 12-13mm total diameter. 4. Modified C loop haptic/plate haptics	Each piece	As per Annexure VIII	
	5. IOL should have UV blocking capability 6. IOL should have 360° square edge 7. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision 8. Diopters- + 18 D to + 24 D at 0.5 D step. 9. Supplying unit should be ISO accredited and IOL should be			
S-	CE/US FDA certified. Foldable Intra Ocular lense with injector (Size + 24.5 D to + 28.5	Each piece	As per	
87(c)	D) Size:6mm optics. 12-13mm total diameter 1. Made of foldable Acrylic (Hydrophobic) material 2. Bi-Convex single piece IOL with as pheric optics		Annexure VIII	
	3. Size:6mm optics. 12-13mm total diameter.4. Modified C loop haptic/plate haptics5. IOL should have UV blocking capability			
	6. IOL should have 360° square edge 7. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision 8. Diopter + 24.5 D to + 28.5 D at 0.5 D step			
	9. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified.			
S- 88(a)		Each piece)	As per Annexure VIII	
	3. IOL haptics – modified C shaped with 5° -10° anterior angulation.			
	5. IOL should have UV blocking capability 6. Diopters - + 11 D to +17.5 D at 0.5 D step.			
S- 88(b)	Standard PMMA Intra Ocular Lenses (Size + 18 D to + 24 D) • 6mm optic size 12.5 - 13.0 mm total diameter, Biconvex	Each piece	As per Annexure VIII	
	2. 6mm optic size 12.5 to 13mm total diameter, Biconvex 3. IOL haptics – modified C shaped with 5°-10° anterior			
	4. Should have 360° square edges.5. IOL should have UV blocking capability			
88	S-	8. Diopters - + 24.5 D to + 28.5 D at 0.5 D step. 9. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. Standard PMMA Intra Ocular Lenses (Size + 11 D to +17.5 D) •6mm optic size 12.5 - 13.0 mm total diameter, Biconvex 1. PMMA optics and haptics single piece with hole 2. 6mm optic size 12.5 to 13mm total diameter, Biconvex 3. IOL haptics – modified C shaped with 5° -10° anterior angulation. 4. Should have 360° square edges. 5. IOL should have UV blocking capability 6. Diopters - + 11 D to +17.5 D at 0.5 D step. 7. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. Standard PMMA Intra Ocular Lenses (Size + 18 D to + 24 D) •6mm optic size 12.5 - 13.0 mm total diameter, Biconvex 1. PMMA optics and haptics single piece with hole 2. 6mm optic size 12.5 to 13mm total diameter, Biconvex 3. IOL haptics – modified C shaped with 5° -10° anterior angulation. 4. Should have 360° square edges.	8. Diopters - + 24.5 D to + 28.5 D at 0.5 D step. 9. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. Standard PMMA Intra Ocular Lenses (Size + 11 D to +17.5 D) •6mm optic size 12.5 - 13.0 mm total diameter, Biconvex 1. PMMA optics and haptics single piece with hole 2. 6mm optic size 12.5 to 13mm total diameter, Biconvex 3. IOL haptics – modified C shaped with 5° -10° anterior angulation. 4. Should have 360° square edges. 5. IOL should have UV blocking capability 6. Diopters - + 11 D to +17.5 D at 0.5 D step. 7. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. Standard PMMA Intra Ocular Lenses (Size + 18 D to + 24 D) •6mm optic size 12.5 - 13.0 mm total diameter, Biconvex 1. PMMA optics and haptics single piece with hole 2. 6mm optic size 12.5 to 13mm total diameter, Biconvex 3. IOL haptics – modified C shaped with 5° -10° anterior angulation. 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.	8. Diopters - + 24.5 D to + 28.5 D at 0.5 D step. 9. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. Standard PMMA Intra Ocular Lenses (Size + 11 D to +17.5 D) • 6mm optic size 12.5 - 13.0 mm total diameter, Biconvex 1. PMMA optics and haptics single piece with hole 2. 6mm optic size 12.5 to 13mm total diameter, Biconvex 3. IOL haptics – modified C shaped with 5° -10° anterior angulation. 4. Should have 360° square edges. 5. IOL should have UV blocking capability 6. Diopters - + 11 D to +17.5 D at 0.5 D step. 7. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. Standard PMMA Intra Ocular Lenses (Size + 18 D to + 24 D) • 6mm optic size 12.5 - 13.0 mm total diameter, Biconvex 1. PMMA optics and haptics single piece with hole 2. 6mm optic size 12.5 to 13mm total diameter, Biconvex 3. IOL haptics – modified C shaped with 5° -10° anterior angulation. 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.

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Test Proposed to be carried out	Remarks
		CE/US FDA certified.			
125.	S- 88(c)	Standard PMMA Intra Ocular Lenses (Size + 24.5 D to + 28.5 D) 6mm optic size 12.5 - 13.0 mm total diameter, Biconvex 1. PMMA optics and haptics single piece with hole 2. 6mm optic size 12.5 to 13mm total diameter, 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 - 24.5 D to + 28.5 D at 0.5 D step. 7. Supplying unit should be ISO accredited and IOL should be	Each piece	As per Annexure VIII	
126.	S-89	CE/US FDA certified. Disposable Sterile Surgical Rubber Gloves Size 8 Inches • made of natural rubber latex-powder free latex free, without tear, properly folded in a paper • Should Conform to IS 13422 • ISI marked/CE certified/FDA approved • Colour code marking to designate size	Pair	As per Annexure VIII	
127.	S- 90(a)	Rubber examination gloves made of natural rubber latex. Non- sterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Extra Small. should conform to IS 15354	Dispenser Box of 100 Gloves	As per Annexure VIII	
128.	S-90 (b)	Rubber examination gloves made of natural rubber latex. Non- sterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Small should conform to IS 15354	Dispenser Box of 100 Gloves	As per Annexure VIII	
129.	S-90 (c)	Rubber examination gloves made of natural rubber latex. Non- sterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Medium should conform to IS 15354	Dispenser Box of 100 Gloves	As per Annexure VIII	
130.	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 should conform to IS 15354	Dispenser Box of 100 Gloves	As per Annexure VIII	
131.	S-91	Pressure Monitoring Line / High Pressure Extension Line Suitable for high pressure monitoring and for connection between syringe infusion pump and patient Male luer lock at one end and female luer lock at other end; should fit all standard equipment. Luer lock connectors should provide secure fitting. Pressure upto 800 psi Length 200 cm Sterile	Each piece in Blister Pack	As per Annexure VIII	
132.	S-92	Urine Collecting Bag for new born / Paediatric urine collecting Bag Should have suitability for both male and female patients Should be provided with adhesive for fixation and good grip with minimal risk of allergy and injury Capacity 100 ml Sterile	Each piece	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with specification	Packing Unit	Test Proposed to be carried out	Remarks
133.	S-93	Umbilical Catheter (for New Born) All sizes Radio opaque line With female flexible mount Colour coded connector Open tip should be soft, rounded, atraumatic Length 40 cm	Each Piece	As per Annexure VIII	
134.	S-94	Umbilical Cord Clamp Suitable for clamping umbilical cord of new born Security lock to prevent accidental opening after clamping Grooved clamping area	Each piece	As per Annexure VIII	
135.	S-95	Absorbable Oxidized Regenerated Cellulose net size 2"x 3" with surgical sponge Topical Absorbable Haemostatic Bactericidal Property	Each piece	As per Annexure VIII	
136.	S- 96A	Close wound Drainage Device under negative pressure (Closed Wound Suction Unit) Option to use one or two catheters simultaneously Bellow chamber with capacity 800 ml Bellow unit with connector Graduated Bellow Connecting tube with clamp and "Y"connector Curved needle / trocar with catheter Multiperforated catheter / Radon drain with radio opaque line Catheter 16 FG	Each Piece(As per Annexure VIII	
137.	S- 96B	Close wound Drainage Device under negative pressure (Closed Wound Suction Unit) Option to use one or two catheters simultaneously Bellow chamber with capacity 800 ml Bellow unit with connector Graduated Bellow Connecting tube with clamp and "Y"connector Curved needle / trocar with catheter Multiperforated catheter / Radon drain with radio opaque line Catheter 18 FG	Each Piece	As per Annexure VIII	
138.	S-97	 T - Tube for Common Bile Duct Drainage 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	As per Annexure VIII	
139.	S-98	Bone cement with antibiotics, fast and slow setting	40 GM PACK	As per Annexure VIII	
		General Specification for S-99(a) and S-99(b) Sanitary Napkins (for Menstrual Hygiene) Specifications: Sanitary Napkin consists of an outer covering provided with sufficient number of channels for leak protection and an absorbent filler material. The Sanitary Napkins shall have a soft feel and when wom shall not chafe or give any uncomfortable feeling. Should be		As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification	Packing Unit	Test Proposed to be carried out	Remarks
		 odourless. The material used in fabrication shall be non allergenic. Shall be free from acids and alkali. Each primary package shall contain 6 napkins in a polyethylene bag of good quality which should conform to size of product and sealed properly. Both upper and lower sheets shall be white in colour. Shall conform to IS 5405. Type of material and size should be mentioned as per IS 5405 Instruction for usage should be mentioned on every packet. 			
140.	S- 99(a)	Sanitary Napkin, Beltless 1. Covering – Covering of the absorbent filler shall be good quality knitted sleeve or non-woven fabric which has sufficient porosity to permit the assembled napkin to meet the absorbency requirements. The napkins shall have a non absorbent barrier on one side which shall have an identifying mark indicating the side of the barrier. 2. Absorbent Filler – The filler material shall consist of cellulose pulp/ wadding, and shall be free from lumps, oil spots, dirt or foreign material, etc. 3. Back Strip – A back strip for sticking the sanitary napkin onto the underwear should be there using good quality adhesive material. 4. Size - The size of absorbent section / complete sanitary napkin shall be as follows: (in mm) Absorbent section Total Pad Length 210 + 10 230 + 10 Width 60 to 75 70 to 85 Thickness 8 + 2 5. Weight: Not more than 10 gm. Instruction for usage should be mentioned on every packet	6 napkins per pack	As per Annexure VIII	
141.	S- 99(b)	Sanitary Napkin, Belttype 1. Covering – Covering of the absorbent filler shall be good quality knitted sleeve or non-wown fabric which has sufficient porosity to permit the assembled napkin to meet the absorbency requirements. The napkins shall have a non absorbent barrier on one side which shall have an identifying mark indicating the side of the barrier. 2. Absorbent Filler – The filler material shall consist of cellulose pulp/ wadding, and shall be free from lumps, oil spots, dirt or foreign material, etc 3. Size - The size of absorbent section / complete sanitary napkin shall be as follows: (in mm) Absorbent section Pad Length Width 70+5 Thickness 17+3 4. Weight: 12+3 gm 5. Pack – Six napkins in a pack. 6. Elastic Belt with loops shall be provided in each pack. 7. Absorbency: The napkin should be able to absorb not less than 30 ml of normal saline or coloured water or test fluid when poured on to the centre of the napkin at the rate of 15 ml per minute. Instruction for usage should be mentioned on every	6 napkins per pack	As per Annexure VIII	

S. No.	Code No.	Name of approved item (s) with s pecification	Packing Unit	Test Proposed to be carried out	Remarks
		packet.			
142.	S- 99(P)	Belt-less Sanitary Napkin with wings 1. Covering –Good Quality knitted sleeve or non woven fabric of rash free,non irritant and soft to touch material which has sufficient porosity to permit the assembled napkin to meet absorbency requirements. The napkins shall have a non absorbent barrier on one side with adhesive covered by a differently identifiable paper 2. Overall Length (mm) 230 ± 5 3. Core length 220 mm± 10 4. Fluff core/pad length 220 mm± 10 5. Over all width with wings 160mm+_5 6. Fluff core/pad length 70 mm± 5 7. Thickness of a single pad 9-10mm 8. Weight of a single pad: 8-10 gm 9. Pack Six napkins in a pack. 10Type Belt-less Sanitary Napkin with wings 11. Minimum Absorbency: 50ml 12. pH value of absorbent material 6-8.5 B. DISPOSABLE Individual pouch or wrapper for each sanitary napkin(as per ministry of environment, forest and climate change dated 08.04. 2016)	6napkins per pack	As per Annexure VIII	
143.	S-102	 Sterile Catheter, single Use, for Urinary Drainage(Foley Baloon Catheter), 2 way, Size 14 Made of Silicone elastomer bonded with Latex Should have hard plastic valve Smooth distal end with smooth eyes for a traumatic intubation Symmetrical Foley Balloon Balloon Capacity 30±1 ml Should conform to IS 11497 Color coding marking to identify size Length, wall thickness and ballon capacity should be mentioned as per IS 11497 Specification for B,C,D,E,F,G should be mentioned as per IS 11497 	Each piece	As per Annexure VIII	

ANNEXURE VIII Clause 2(8)

		Surgicals	s Items - Te	sting P	arameters
Sr. No	Code No.	Item Description	Unit		Test proposed to be carried out (Standard)
1	S-1	Absorbable Gelatin Sponge IP	Piece	A	Physical
		66, Size 80 +-10 mm x 50 mm		1	Description
		x 10 mm . Should be sterlised		В	Chemical
				1	Water Absorbance
				2	Density
				3	Formaldehyde
				4	Total Nitrogen
				5	Ash
				6	Water
				С	Biological Test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
2	S-2	Absorbent Cotton Wool IP 500	Packet	A	Physical
		gm		1	Description
				2	Colouring Matter
				В	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
					Absorbency A Sinking Time
					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
		Transparent Bulb, Sterile, 60 ml			Description
		1111			Components
					Freedom from extraneous Matter
					Leakage
					Capacity

					Transparency
				В	Biological Test
					Sterility
					Pyrogen / Bacterial Endoto xins Test
4	S-4	Blood Admin istration Set /	Unit	A	Physical
		Blood Transfusion Set Conforms to IS 9824-3:1996		1	Tubing (Length, Internal Dia., other properties-kink resistance, transparency)
				2	Closure -Piercing Device
				3	Connection between male fiting, injection site and tubing
				4	Air - inlet device
				5	Filter
				6	Drip chamber and drip tube
				7	Flow Regulator
				8	Test for injection Site
				9	Test for Integrity
				10	Protective Cap
				11	Blood Flow Rate
				12	Male Fitting
				13	Test for filter efficiency
				В	Chemical test
				1	Reducing (Oxidizable) Matter
				2	Heavy Metal Ions
				3	Acidity or Alkalinity
				4	Residue on evaporation
				5	Absorbance
				С	Biological Test
				1	Sterility Test
				2	Pyrogen / Bacterial Endotoxins Test
				3	Toxicity Test
5	S-5	Disposable Sterile Surgical	Pair	Α	Physical
		Rubber Gloves, Size 6½ Inches		1	Dimension
		IS 13422		2	Thickness
				3	Cuff
				4	Tensile Strength (Mpa) (Before Ageing)
				5	Tensile Strength (Mpa) (After Ageing)
				6	Elongation at break (%) (Before Ageing)
				7	Elongation at break (%) (After Ageing)
				8	Stress at 500% (Mpa) (Before Ageing)
				9	Air Tight Test
				В	Biological Test
		ı	1	1	ı

				1	Sterility
6	S-6	Disposable Sterile Surgical	Pair	A	Physical
		Rubber Gloves Size 7 Inches		1	Dimension
		IS 13422		2	Thickness
				3	Cuff
				4	Tensile Strength (Mpa) (Before Ageing)
				5	Tensile Strength (Mpa) (After Ageing)
				6	Elongation at break (%) (Before Ageing)
				7	Elongation at break (%) (After Ageing)
				8	Stress at 500% (Mpa) (Before Ageing)
				9	Air Tight Test
				В	Biological Test
				1	Sterility
7	S-7	Disposable Sterile Surgical	Pair	A	Physical
		Rubber Gloves Size 7½ Inches		1	Dimension
		IS 13422		2	Thickness
				3	Cuff
				4	Tensile Strength (Mpa) (Before Ageing)
				5	Tensile Strength (Mpa) (After Ageing)
				6	Elongation at break (%) (Before Ageing)
				7	Elongation at break (%) (After Ageing)
				8	Stress at 500% (Mpa) (Before Ageing)
				9	Air Tight Test
				В	Biological Test
				1	Sterility
8	S-8	Suction Catheter, Sterile: FG	Each	A	Physical
		5,6,8,10,12,14,16,18,20,22 ISO 8836:2014	Piece	1	Description
		150 8830.2014		2	Shape and dimensions
				3	Length
				4	Funnel Connector
				5	Diameter of Tube
				6	Joint Strength / Security of construction
				7	Elongation Test
				8	Residual Vacuum
				В	Biological Test
				1	Sterility
9	S-9	Sterile Catheter, Single Use,	Each	A	Physical
		for Urinary Drainage (Foley	Piece	1	Description
		Balloon Catheter), 2 Way, Size 8 FG, 10FG, 16FG, 18FG,		2	Shape and dimensions
		20FG, 22FG, 24FG		3	Length of catheter
		IS 11497		4	Valve

				5	Ballon Capacity
				6	Diameter of Catheter
				7	Tensile strength of rubber
				8	Balloon Leakage
				9	Workmanship and surface finish
				В	Chemical test
				1	pH of water extract
				2	Extractable Colour
				3	Heavy metals
				С	Biological Test
				1	Sterility
10	S-10	Infant Feeding Tube Size		A	Physical
		10FG, 8FG, 5FG, Length 50cm		1	Description
				2	Radio opaque line
				4	Particulate Matter
				5	Components
				6	Leakage
				В	Biological Test
				1	Sterility
				2	Toxicity
				3	Pyrogen / Bacterial Endotoxins Test
11	S-11	Sterile Disposable Perfusion	Unit	A	Physical
		Set with Airway and Needle (Adult Use)		1	Description
				2	Tubing (Length, other properties - fle xibility,
		IS 12655- 4		_	transparency)
		IS 12655- 4		3	
		IS 12655- 4			transparency)
		IS 12655- 4		3	transparency) Test of Integrity
		IS 12655- 4		3	transparency) Test of Integrity Connection between components Closure piercing device
		IS 12655- 4		3 3 4	transparency) Test of Integrity Connection between components
		IS 12655- 4		3 3 4 5	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube
		IS 12655- 4		3 3 4 5 6	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube Air inlet device
		IS 12655- 4		3 3 4 5 6 7	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube Air inlet device Flow Rate
		IS 12655- 4		3 3 4 5 6 7 8	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube Air inlet device Flow Rate Flow Regulator
		IS 12655- 4		3 3 4 5 6 7 8	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube Air inlet device Flow Rate Flow Regulator Latex Bulb
		IS 12655- 4		3 3 4 5 6 7 8 9	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube Air inlet device Flow Rate Flow Regulator Latex Bulb Male Fitting
		IS 12655- 4		3 3 4 5 6 7 8 9 10	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube Air inlet device Flow Rate Flow Regulator Latex Bulb Male Fitting Test for efficiency of fluid filter
		IS 12655- 4		3 3 4 5 6 7 8 9 10 11	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube Air inlet device Flow Rate Flow Regulator Latex Bulb Male Fitting Test for efficiency of fluid filter Test of Injection site
		IS 12655- 4		3 3 4 5 6 7 8 9 10 11 12 13	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube Air inlet device Flow Rate Flow Regulator Latex Bulb Male Fitting Test for efficiency of fluid filter Test of Injection site Particulate contamination
		IS 12655- 4		3 3 4 5 6 7 8 9 10 11 12 13	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube Air inlet device Flow Rate Flow Regulator Latex Bulb Male Fitting Test for efficiency of fluid filter Test of Injection site Particulate contamination Protective Cap
		IS 12655- 4		3 3 4 5 6 7 8 9 10 11 12 13 14 B	transparency) Test of Integrity Connection between components Closure piercing device Drip chamber and drip tube Air inlet device Flow Rate Flow Regulator Latex Bulb Male Fitting Test for efficiency of fluid filter Test of Injection site Particulate contamination Protective Cap Chemical test

	5	Metalions
))	Non Volatile Residue
	С	Biological Test
	1	Sterility Test
	2	Pyrogen / Bacterial Endotoxins Test
	3	Toxicity Test
12 S-12 Sterile Disposable Perfusion Unit	A	Physical
Set (Infusion set) with Airway	1	Description
and Needle (Paediatric Use) (with Burette type measured	2	Test of Integrity
volume chamber)	3	Connection between components
ISO 8536-5	4	Closure piercing device
	5	Protective Cap
	6	Drip chamber and drip tube
	7	Flow Rate
	8	Flow Regulator
	9	Injection port
	10	Male Fitting
	11	Burette (capacity, transparency, graduations,
		etc.)
	12	Floating valve (shut off valve) function
	13	Test for efficiency of fluid filter
	14	Test of Injection site
	15	Particulate contamination
	В	Chemical test
	1	Acidity or Alkalinity
	2	Conductivity of extract
	3	Reducing (Oxidizable) Substance
	4	Metal ions
	5	Non Volatile Residue
	С	Biological Test
	1	Sterility Test
	2	Pyrogen / Bacterial Endotoxins Test
	3	Toxicity Test
13 S-13 Sterile Disposable Infusion Set Unit	A	Physical
with Microdip (I.V) IS 12655-4	1	Description
13 12033-4	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 Test of Injection site 13 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 Endoto xins Test 3 Toxicity Test 4 Insulin syringe (40 units) with (fixed) 30 G needle IS 12227 Unit A Physical 1 Description 2 Dimensions 3 Components	
11 Test for efficiency of fluid filter 12 Test of Injection site 13 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 Endoto xins Test 3 Toxicity Test 4 Insulin syringe (40 units) with (fixed) 30 G needle IS 12227 Unit A Physical 1 Description 2 Dimensions 3 Components	
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13 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 4 Physical 1 Description 2 Dimensions 3 Components	
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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 Endoto xins Test 3 Toxicity Test 4 S-14 Insulin syringe (40 units) with (fixed) 30 G needle IS 12227 UV Absorbency of extract A Pleavy Metal Ions 5 Residue on evaporation C Biological Test 1 Sterility Test 1 Description 2 Dimensions 3 Components	
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 4 S-14 Insulin syringe (40 units) with (fixed) 30 G needle IS 12227 Unit Physical 1 Description 2 Dimensions 3 Components	
4 Heavy Metal Ions 5 Residue on evaporation C Biological Test 1 Sterility Test 2 Pyrogen / Bacterial Endotoxins Test 3 Toxicity Test 4 S-14 Insulin syringe (40 units) with (fixed) 30 G needle IS 12227 Unit A Physical 1 Description 2 Dimensions 3 Components	
5 Residue on evaporation C Biological Test 1 Sterility Test 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity Test 4 S-14 Insulin syringe (40 units) with (fixed) 30 G needle IS 12227 Unit A Physical 1 Description 2 Dimensions 3 Components	
C Biological Test 1 Sterility Test 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity Test Hunit (fixed) 30 G needle IS 12227 Unit Description 2 Dimensions 3 Components	
1 Sterility Test 2 Pyrogen / Bacterial Endoto xins 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	
2 Pyrogen / Bacterial Endoto xins 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	
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	
14 S-14 Insulin syringe (40 units) with (fixed) 30 G needle IS 12227 Unit A Physical 1 Description 2 Dimensions 3 Components	
(fixed) 30 G needle IS 12227 1 Description 2 Dimensions 3 Components	
IS 12227 2 Dimensions 3 Components	
2 Dimensions 3 Components	
4 Freedom from extraneous Matter	
5 Properties of needle	
6 Fit of piston in barrel (Test for force r operate plunger)	quired to
7 Dead space	
8 Leakage at needle	
9 Leakage past piston	
10 Markings and Graduations	
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 Sterile Disposable (Single Use) Each A Physical	
Teflon/ PTFE I.V. Cannula Piece 1 Description	
cock. Size 16G, 18G, 20G, 22G IS 10555	e length)
And Sterile Disposable (Single 3 Surface (free from extraneous matter)	
Use) Teflon/PTFE IV Cannula 4 Force at Break	
without port 24G IS 10555 5 Freedom from liquid leakage under pr	

				6	Freedom from air leakage into hub assembly
				7	Needle and fittings
				8	Flow rate
				9	Needle properies (material, design, needle
					point, needle hub, strength of union between hub and needle tube)
				10	Vent fitting (Test for liquid leakage from vent fiting)
				В	Chemical Test
				1	Corrosion Resistance
				С	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
				В	Biological Test
				1	Sterility
				2	Toxicity
17	S-17	Nasal Oxygen Cannula (Set),	Each	A	Physical
		Twin Bore (accessory for compressed air breathing) All	Piece	1	Description
		Sizes (Adult & Paediatric)		2	Components
				3	Particulate Matter
				4	Tube Length
				5	Connector
				6	Multi channel tube properties
				7	Integrity
				8	Leakage
				В	Biological Test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
				3	Toxicity
18	S-18	Paper Adhesive Plaster 1" X	Unit	A	Physical
		9.0 mts (with cutter) Non		1	Description
		woven adhesive tape		2	Dimension (Length, width)
				3	Tensile strength
				4	Adhesive strength

19	S-19	Paper Adhesive Plaster 2" X	Unit	A	Physical
		9.0 mts (with cutter) Non		1	Description
		woven adhesive tape		2	Dimension (Length, width)
				3	Tensile strength
				4	Adhesive strength
20	S-20	Paper Adhesive Plaster 3" X	Unit	A	Physical
		9.0 mts (with cutter) Non woven adhesive tape		1	Description
		woven adhesive tape		2	Dimension (Length, width)
				3	Tensile strength
				4	Adhesive strength
21	S-21	Plaster of Paris Bandages 15cm	Unit	A	Physical
		X 2.7mts / Roll		1	Description
				2	Weight per unit area of Bandage & fabric
				В	Chemical Test
				1	Fiber Identification
					Identification A (Cotton)
					Identification B (Iodinated Zinc Chloride
					Solution Test)
					Identification C (Solubilty in Sulphuric Acid)
					Identification D (Zinc Chloride Solution Test)
				2	Threads per unit area (warp, weft)
				3	Setting time
				4	Content of Calcium sulphate hemihydrate
22	S-22	Plaster of Paris Bandages 10cm	Unit	A	Physical
		X 2.7mts / Roll		1	Description
				2	Weight per unit area of Bandage & fabric
				В	Chemical Test
				1	Fiber Identification
					Identification A (Cotton)
					Identification B (Iodinated Zinc Chloride
					Solution Test)
					Identification C (Solubilty in Sulphuric Acid)
					Identification D (Zinc Chloride Solution Test)
				2	Threads per unit area (warp, weft)
				3	Setting time
1				4	Content of calcium sulphate Hemihydrate

23	S-23	Ryle's Tube / Nasogastric Tube	Each	A	Physical
		Size: 10,12	Piece	1	Description
				2	Components
				3	Radio opaque line
				4	Markings
				5	Funnel luer connector/closure
				6	Length
				7	Particulate Matter
				8	Leakage
				В	Biological Test
				1	Sterility
				2	Toxicity
				3	Pyrogen / Bacterial Endotoxins Test
24	S-24	Ryle's Tube / Nasogastric Tube	Each	A	Physical
		Size: 14,16,18	Piece	1	Description
				2	Components
				3	Radio opaque line
				4	Markings
				5	Funnel luer connector/closure
				6	Length
				7	Particulate Matter
				8	Leakage
				В	Biological Test
				1	Sterility
				2	Toxicity
				3	Pyrogen / Bacterial Endotoxins Test
25	S-25	Scalp Vein Set (Disposable):		A	Physical
		Size 18G, 20G, 22G,24G		1	Description
				2	Cleanliness
				3	Adapter
				4	Wing
				5	Sheath
				6	Needle length
				7	Needle Point
				8	Performance
					a. Bond between wing and needle tube
					b. Bond between wing and extension tube
					c. Bond between extension tube & adapter
				В	Chemical
				1	Acidity or Alkalinity
				2	Extractable metals

				С	Bioloical Test
				1	Sterility
				2	Toxicity
				3	Pyrogen / Bacterial Endotoxins Test
26	S-26	Sterile Hypodermic Syringe	Unit	A	Physical
		with Needle attached, 24G,		1	Description
		Single 2ml IS 12050		2	Components
				3	Cleanliness
				4	Lubrication
				5	Tolerance on graduated Capacity
				6	Fit of Piston in barrel
				7	Needle Attachment
				8	Needle dimensions
				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	Bond between hub/syringe barrel and needle tube
				b	Patency of lumen
				11	Dead space
				В	Chemical test
				1	Acidity or Alkalinity (pH)
				2	Extractable Metals
				С	Biological test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
				3	Toxicity
27	S-27	Sterile Hypodermic Syringe	Unit	A	Physical
		with Needle attached, 24G Single Use - 5 ml		1	Description
		IS 12050		2	Components
				3	Cleanliness
				4	Lubrication
				5	Tolerance on graduated Capacity
				6	Fit of Piston in barrel
				7	Needle Attachment
				8	Needle dimensions
				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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH) 2 Estractable Metals C Biological test 1 Sterility 2 Pyrogen / Bacterial Endotoxins Test 3 Toxic ity 2 Pyrogen / Bacterial Endotoxins Test 1 Description 2 Components 3 Cleanliness 4 Lubrication 5 Tokerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 compression 10 Test for Needle assembly a Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH) 2 Estractable Metals						Liquid leakage past the syringe piston and at		
syringe needle union during aspiration 10 Test for Needle assembly a Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH) 2 Extractable Metals C Biological test 1 Sterility 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity 4 Physical with Needle attached, 22G, Single Unit Single Use - 10 ml IS 12050 10 Description 2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 10 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					a			
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tube b Patency of lumen 11 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 4 Physical 1 Description 2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/ syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)						-		
11 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 2 Pyrogen / Bacterial Endotoxins Test 3 Toxicity A Physical 1 Dead space Description 2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					u u	tube		
B Chemical test 1 Acidity or Alkalinity (pH) 2 Extractable Metals C Biological test 1 Sterility 2 Pyrogen / Bacterial Endotoxins Test 3 Toxicity A Physical 1 Description 2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					b	Patency of lumen		
S-28 S-28 Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 10 ml IS 12050 Unit IS 12050					11	_		
2 Extractable Metals C Biological test 1 Sterility 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity A Physical 1 Description 2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/ syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					В	Chemical test		
C Biological test					1			
S-28 S-28 Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 10 ml IS 12050 Unit IS 12					2	Extractable Metals		
2 Pyrogen / Bacterial Endotoxins Test 3 Toxicity A Physical Unit Description 2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					С	Biological test		
3 Toxicity 28 S-28 Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 10 ml IS 12050 Unit 4 Physical 1 Description 2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					1	Sterility		
S-28 Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 10 ml IS 12050 A Physical 1 Description 2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					2	Pyrogen / Bacterial Endotoxins Test		
with Needle attached, 22G, Single Use - 10 ml IS 12050 1 Description 2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/ syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					3	Toxicity		
Single Use - 10 ml IS 12050 2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/ syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)	28	S-28		Unit	A	Physical		
2 Components 3 Cleanliness 4 Lubrication 5 Tolerance on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					1	Description		
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6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					4	Lubrication		
7 Needle Attachment 8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					5	Tolerance on graduated Capacity		
8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					6	Fit of Piston in barrel		
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 Bond between hub/ syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					7	Needle Attachment		
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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					8	Needle dimensions		
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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					9	Leakage Test		
syringe needle union during aspiration 10 Test for Needle assembly a Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)							a	Liquid leakage past the syringe piston and at the syringe needle union during compression
a Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)				b				
a Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)				10	Test for Needle assembly			
b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					Bond between hub/syringe barrel and needle			
11 Dead space B Chemical test 1 Acidity or Alkalinity (pH)					b			
1 Acidity or Alkalinity (pH)					11	Dead space		
					В	Chemical test		
					1	Acidity or Alkalinity (pH)		
					2	-		
C Biological test					С	Biological test		

2 Pyrogen / Bacterial Endotoxins Test 3 Toxicity 4 Physical 5 Pyrogen / Bacterial Endotoxins Test 6 Pyrogen / Bacterial Endotoxins Test 7 Poscription 8 Pyrogen / Bacterial Endotoxins Test 1 Description 2 Components 3 Cleanliness 4 Lubrication 5 Tokenace on graduated Capacity 6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 9 Leakage Test 1 Leakage Test 1 Leakage Test 2 Leakage Test 3 Liquid leakage past the syringe piston and at the syringe needle union during compression 6 Air leakage past the syringe piston and at the syringe needle union during compression 10 Test for Needle assembly a Bond between hub/syringe barrel and needle tube b Patency of lumen 11 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 4 Pyrogen / Bacterial Endotoxins Test 3 Toxicity 4 Performance Test 5 B Biological Test 5 Sterility 5 Physical 6 Physical 7 Physical 8 Physical 9 Pyrogen / Bacterial Endotoxins Test 1 Sterility 3 Shape and Dimensions 4 Performance Test 5 B B Biological Test 5 Sterility 5 Physical 6 Pist of Piston in barrel 7 Postical 7 Postical 8 Physical 9 Pyrogen / Bacterial Endotoxins Test 9 Pyrogen / Bacterial Endotoxins Test 1 Sterility 1 Sterility 2 Pyrogen / Bacterial Endotoxins Test 3 Pyrogen / Bacterial Endotoxins Test 4 Performance Test 5 B B Biological Test 5 Pkt 7 Pkt 8 Pkt 9 Pyrogen / Bacterial Endotoxins Test 9 Pkt 1 Patency of lumen 1 Patency of lumen 1 Patency of lumen 1 Patency of lumen 2 Patency of lumen 3 Pkt 4 Performance Test 5 Pkt 5 Pkt 6 Pkt					1	Sterility
S-29 Sterile Hypodemic Syringe with Needle attached, 22G, Single Use - 20 ml IS 12050 IS 1205					2	Pyrogen / Bacterial Endotoxins Test
with Needle attached, 22G, Single Use - 20 ml IS 12050 1					3	, ,
with Needle attached, 22G, Single Use - 20 ml IS 12050 1	29	S-29	Sterile Hypodermic Syringe	Unit	A	Physical
Single Use - 20 ml IS 12050			with Needle attached, 22G,			-
3 Cleanliness 4 Lubrication					2	_
S			13 12030		3	_
6 Fit of Piston in barrel 7 Needle Attachment 8 Needle dimensions 9 Leakage Test a Liquid leakage past the syringe piston and at the syringe needle union during compression					4	Lubrication
7 Needle Attachment 8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH) 2 Extractable Metals C Biological test 1 Sterility 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity 4 Performance Test B Biological Test 1 Sterility 3 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 Size, Shape and dimensions 3 Size, Shape and Size, Shape					5	Tolerance on graduated Capacity
8 Needle dimensions 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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 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 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 4 Performance Test B Biological Test 1 Sterility 5 Sterility 7 Physical 1 Sterility 8 Physical 1 Sterility 9 Physical 1 Sterility 1 Sterility 1 Sterility 1 Sterility 1 Sterility					6	Fit of Piston in barrel
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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 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 A Physical 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 4 Performance Test B Biological Test 1 Sterility 5 Sterility 7 Pst. 1 Sterility 8 Proformance Test 1 Sterility 1 Sterility 1 Sterility 2 Pyrogen / Bacterial Endotoxins Test 3 Toxicity 4 Physical 5 Sterile Size: 1 Sterility 4 Performance Test 5 Biological Test 1 Sterility 1 Sterility 3 Physical					7	Needle Attachment
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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH) 2 Extractable Metals C Biological test 1 Sterility 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity A Physical 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 4 Performance Test B Biological Test 1 Sterility 5 Sterility 7 Pkt. 1 Sterility 1 Sterility 1 Sterility 4 Performance Test B Biological Test 1 Sterility 3 Sterility 4 Physical 5 Sterility					8	Needle dimensions
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 Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH) 2 Extractable Metals C Biological test 1 Sterility 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 4 Performance Test B Biological Test 1 Sterility A Physical 1 Sterility A Physical 1 Sterility A Physical 3 Visual Examination (particularly for nicks)					9	Leakage Test
syringe needle union during aspiration 10 Test for Needle assembly a Bond between hub/syringe barrel and needle tube b Patency of lumen 11 Dead space B Chemical test 1 Acidity or Alkalinity (pH) 2 Extractable Metals C Biological test 1 Sterility 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity A Physical 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 3 Serility 4 Performance Test 5 B Biological Test 6 Nos. 7 Circle Round Body Assorted 5 Size, Shape and dimensions 6 Nos. 7 Pkt. 1 Size, Shape and dimensions					a	
a Bond between hub/syringe barrel and needle tube b Patency of lumen 11 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 4 Physical 1 Shape and Dimensions Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 4 Performance Test B Biological Test 1 Sterility A Physical 1 Sterility 4 Performance Test B Biological Test 1 Sterility A Physical 1 Sterility 4 Performance Test B Biological Test 1 Sterility A Physical 1 Sterility 31 S-31 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15					b	
a Bond between hub/syringe barrel and needle tube b Patency of lumen 11 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 4 Physical 1 Shape and Dimensions Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 4 Performance Test B Biological Test 1 Sterility A Physical 1 Sterility 4 Performance Test B Biological Test 1 Sterility A Physical 1 Sterility 4 Performance Test B Biological Test 1 Sterility A Physical 1 Sterility 31 S-31 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15					10	Test for Needle assembly
11 Dead space					a	Bond between hub/syringe barrel and needle
B Chemical test 1 Acidity or Alkalinity (pH) 2 Extractable Metals C Biological test 1 Sterility 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity A Physical 11,15,22 Biological test 1 Sterility 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity A Physical 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 31 S-31 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 A Physical 1 Size, Shape and dimensions					b	Patency of lu men
30 S-30 Surgical Blade, Sterile Size: 1					11	Dead space
2 Extractable Metals C Biological test 1 Sterility 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity 30 S-30 Surgical Blade, Sterile Size: 11,15,22					В	Chemical test
S-30 S-30 Surgical Blade, Sterile Size: 1					1	Acidity or Alkalinity (pH)
30 S-30 Surgical Blade, Sterile Size: 11,15,22 100 blades / Pkt A Physical 1 Sterility 2 Pyrogen / Bacterial Endoto xins Test 3 Toxicity A Physical 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 31 S-31 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 A Physical 1 Sterility 4 Performance Test B Biological Test 1 Sterility 4 Physical 1 Sterility					2	Extractable Metals
30 S-30 Surgical Blade, Sterile Size: 100 blades / Pkt 11,15,22 3 Pyrogen / Bacterial Endoto xins Test 3 Toxicity A Physical 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 31 S-31 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 A Physical 1 Size, Shape and dimensions					С	Biological test
3 Toxicity 3 Toxicity A Physical 11,15,22 A Physical 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 3 Toxicity A Physical 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 3 Sterility 3 Toxicity A Physical 1 Shape and Dimensions 4 Performance Test B Biological Test 1 Sterility 3 Sterility 3 Sterility 3 Sterility					1	Sterility
30 S-30 Surgical Blade, Sterile Size: 100 blades / Pkt 1 Shape and Dimensions 2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 31 S-31 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 6 Nos. /Pkt. 2 Physical 1 Shape and Dimensions 4 Performance Test B Biological Test 1 Sterility 4 Physical 1 Size, Shape and dimensions					2	Pyrogen / Bacterial Endotoxins Test
blades / Pkt 1					3	Toxicity
Pkt Pkt Pkt Shape and Diffensions	30	S-30			A	Physical
2 Hardness test 3 Visual Examination (particularly for nicks) 4 Performance Test B Biological Test 1 Sterility 31 S-31 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 A Physical 1 Size, Shape and dimensions			11,15,22		1	-
4 Performance Test B Biological Test 1 Sterility 31 S-31 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 A Physical 1 Size, Shape and dimensions				T Kt	2	Hardness test
B Biological Test 1 Sterility 31 S-31 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 B Biological Test 1 Sterility 1 Size, Shape and dimensions					3	Visual Examination (particularly for nicks)
31 S-31 Suture Needles Curved 1/2 Circle Round Body Assorted Size 11-15 1 Sterility A Physical 1 Size, Shape and dimensions					4	Performance Test
31 S-31 Suture Needles Curved 1/2 6 Nos. A Physical Circle Round Body Assorted Size 11-15 Size, Shape and dimensions					В	Biological Test
Circle Round Body Assorted Size 11-15 /Pkt. 1 Size, Shape and dimensions					1	Sterility
Size 11-15	31	S-31			A	Physical
				/Pkt.	1	Size, Shape and dimensions
Should contour to 10 / 100			Should conform to IS-9165		2	Hardness test

				3	Free from surface defects (Feather edges, burrs, nicks)
				4	Flexibility
				5	Sharpness
				В	Chemical Test
				1	Corrosion Resistance test
32	S-32	Suture Needles Curved 1/2	6 Nos.	A	Physical
02	2 02	Circle Round Body Assorted	/Pkt.	1	Size, Shape and dimensions
		Size 1-5		2	Hardness test
		Should conform to IS-9165		3	Free from surface defects (Feather edges, burrs,
					nicks)
				4	Flexibility
				5	Sharpness
				В	Chemical Test
				1	Corrosion Resistance test
33	S-33	Suture Needles Curved 1/2	6 Nos.	A	Physical
		Circle Round Body Assorted Size 16-20	/Pkt.	1	Size, Shape and dimensions
		Should conform to IS-9165		2	Hardness test
				3	Free from surface defects (Feather edges, burrs, nicks)
				4	Flexibility
				5	Sharpness
				В	Chemical Test
				1	Corrosion Resistance test
34	S-34	Suture Needles Curved 1/2	6 Nos.	A	Physical
		Circle Round Body Assorted	/Pkt.	1	Size, Shape and dimensions
		Size 6-10 Should conform to IS-9165		2	Hardness test
		2.10 2.20		3	Free from surface defects (Feather edges, burrs, nicks)
				4	Flexibility
				5	Sharpness
				В	Chemical Test
				1	Corrosion Resistance test
35	S-35	Suture Needles Curved And	6 Nos./	A	Physical
		Cutting 1/2 Circle Cutting Size	Pkt.	1	Size, Shape and dimensions
		6-10 Should conform to IS-9165		2	Hardness test
		2.104.6 00.1101.11 00 15 7100		3	Free from surface defects (Feather edges, burrs, nicks)
				4	Flexibility
				5	Sharpness
				В	Chemical Test
				1	Corrosion Resistance test
36	S-36	Suture Needles Curved And	6 Nos./	A	Physical
23	~ 20		2 1.00.7		V

		Cutting 1/2 Circle Size 11-15	Pkt.	1	Size, Shape and dimensions
		3		2	Hardness test
				3	Free from surface defects (Feather edges, burrs, nicks)
				4	Flexibility
				5	Sharpness
				В	Chemical Test
				1	Corrosion Resistance test
37	S-37	Suture Needles Curved And	6 Nos.	A	Physical
		Cutting 1/2 Circle Size 16-20	/Pkt.	1	Size, Shape and dimensions
				2	Hardness test
				3	Free from surface defects (Feather edges, burrs, nicks)
				4	Flexibility
				5	Sharpness
				В	Chemical Test
				1	Corrosion Resistance test
38	S-38	Suture Needles Curved And	6 Nos./	A	Physical
		Cutting Size 1-5	Pkt	1	Size, Shape and dimensions
		Should conform to IS-9165		2	Hardness test
				3	Free from surface defects (Feather edges, burrs, nicks)
				4	Flexibility
				5	Sharpness
				В	Chemical Test
				1	Corrosion Resistance test
39	S-39	Sterile Disposable Spinal	Each	A	Physical
		Needle for Single Use 22G x 3 ½ inch & 25G x 3 1/2 inch	Piece	1	Description
		72 men & 230 x 3 1/2 men		2	Dimensions
				1	Leakage Test
				2	Sharpness of Needle point
				3	Elasticity
				4	Reverse Bend Test
				5	Stiffness
				6	Security of Swaging
				7	Freedom from Foreign Matter
				В	Chemical Test
				1	Corrosion Resistance
				С	Biological Test
				1	Sterility
				2	Toxicity

40	S-40	Urine Collecting Bag,	Unit	A	Physical
		Disposable, 2000 ml		1	Description
				2	Components
				3	Non-return valve
				4	Leakage
				В	Biological Test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
				3	Toxicity
41	S-41	Double J Stent, Sterile, Both	Each	A	Physical
		Ends Open, size 4F & 5F,	Piece	1	Length of Stent
		length 16/20 cm		2	O.D. Of Stent
				3	I.D. Of Stent
				4	Length of pusher
				5	OD of guidewire
				6	Visual Test
					Surface of stent
					Quality of J Stent tip
					Quality of Pusher
					Position of X-ray Line
				7	Performance test: Movement of guidewire in J
					stent
				В	Biological Test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
				3	Toxicity
41	S-42	Double J Stent, Sterile, One	Each	A	Physical
		End Closed, size 4F & 5F, length 16/20 cm	Piece	1	Length of Stent
		length 107 20 cm		2	O.D. Of Stent
				3	I.D. Of Stent
				4	Length of pusher
				5	OD of guidewire
				6	Visual Test
					Surface of stent
					Quality of J Stent tip
					Quality of Pusher
					_
				7	Quality of Pusher
				7 B	Quality of Pusher Position of X-ray Line Performance test: Movement of guidewire in J stent
					Quality of Pusher Position of X-ray Line Performance test: Movement of guidewire in J stent Biological Test
				В	Quality of Pusher Position of X-ray Line Performance test: Movement of guidewire in J stent

				3	Toxicity
43	S-43	Endotracheal Tube, Size: 2.5,		A	Physical
		3, 3.5, 4,4.5,5,5.5,			
		6,6.5,7,7.5,8,8.5,		1	Description
				2	Dimensions
				a	Inside Diameter
				b	Outside Diameter
				С	Curvature
				d	Bevel
				e	Length
				3	Design Features and Finish
				В	Biological Test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
				3	Toxicity
44	S-44	Endotracheal Tube, Cuffed –		A.	Physical
		Size:4,4.5,5,6,6.5,7,7.5,8,8.5,9		1	Description
				2	Dimensions
				a	Inside Diameter
				b	Outside Diameter
				С	Curvature
				d	Bevel
				e	Length
				3	Cuff
				a	Inflating of cuff
				b	Cuff resting diameter
				С	Tube Collapse test
				d	Cuff herniation test
				4	Design Features and Finish
				В	Biological Test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
				3	Toxicity
45	S-45	Tracheostomy Tube (PVC),	Each	A	Physical
		Plain, Sterile, Single Use - All Sizes	Piece	1	Dimensions
		51208		a	Nominal Length
				b	O.D. of Tube
				с	I.D. of Tube
				d	Angle
				2	Design Features and Finish
				a	Conical Connector
				b	Neck-Plate

46	S-46	Tracheostomy Tube (PVC), Cuffed, Sterile, Single Use - All Sizes	Each Piece	3 4 B 1 2 3 A 1 a b c d 2	Test for attachment of connector & neck plate to the tube Packaging Biological Test Sterility Test Pyrogen / Bacterial Endoto xins Test Toxicity Physical Dimensions No minal Length O.D. of Tube I.D. of Tube Angle Design Features
				a b c d 3 4 5 6 B 1 2 3	Conical Connector Neck-Plate Cuff Inflating tube for cuff Test for attachment of connector & neck plate to the tube Resting diameter of cuff Design finish Packaging Biological Test Sterility Test Pyrogen / Bacterial Endoto xins Test Toxicity
47	S-47	Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag (2000 ml) Size 24, 28, 32	Each Piece	A 1 2 3 4 5 6 7 8 9 B 1 2 3	Physical Description Transparency Kink resistant and flexible tube Length Width Non-return valve Graduation Capacity Leakage of Bag Biological Test Sterility Test Pyrogen / Bacterial Endoto xins Test Toxicity
48	S-48	Corrugated Drainage Sheet, Sterile, Multichannel, with	Each Piece	A 1	Physical Description

		radio opaque line, Single Use -		2	Radio opaque line
		All sizes		3	Multichannel
				4	Performance
				В	Biological Test
				1	Sterility Test
49	S-73	Polypropylene Nonabsorbable	Piece	A	Physical
		Synthetic Surgical Mesh 7.5		1	Dimensions
		cm X 15 cm		2	Surface Weight
				3	Straight pull tensile strength lengthwise
				4	Straight pull tensile strength crosswise
				5	Elongation lengthwise
				6	Elongation crosswise
				В	Biological Test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
50	S-74	Polypropylene Nonabsorbable	Piece	A	Physical
		Synthetic Surgical Mesh 15 cm X 15 cm		1	Dimensions
		X 15 cm		2	Suface Weight
				3	Straight pull tensile strength lengthwise
				4	Straight pull tensile strength crosswise
				5	Elongation lengthwise
				6	Elongation crosswise
				В	Biological Test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
51	S-79	Sterilised Umbilical Cotton	Each	A	Physical
		Tape Width 3 mm, Length 75 cm	Piece	1	Colour
		CIII		2	Length
				3	Width
				4	Tensile Strength
				В	Biological Test
				1	Sterility Test
52	S-80	Bone Wax, Sterilised	2g m/Pkt	A	Physical
				1	Average Weight
				2	Weight Variation
				В	Chemical Test
				1	Acid Value
				2	Saponification
				С	Biological Test
				1	Sterility
53	S-81	Temporary Cardiac Pacing	Sachet	Α	Physical
		Wire (Electrode) Sterile ½ Cir,		1	Description

		Tapercut, 26 mm; Straight		2	Visual Testing
		cutting 60mm, breakaway		3	Resistance
				4	Strand Length
				5	Diameter
				6	Needle Testing
				7	Tensile Testing
				В	Biological Test
				1	Sterility
54	S-82	Skin Graft Knife Blade	One Pack	Α	Physical
		(Sterile, disposable); and	each	1	Shape and Dimensions
		Handle (Watson modification of Humby's Knife)		2	Blade hardness
		orraniby s kinic)		3	Finishing
				4	Performance test
				В	Chemical Test
				1	Corrosion Resistance
				С	Biological Test
				1	Sterility
55	S-84	K Wire, length 375 mm; 1	Each unit	A	Physical
		mm, 1.6mm, 1.8mm IS - 8261		1	Ends
		13 - 0201		2	Diameter
				3	Length
				4	Tensile Strength
				В	Chemical Test
				1	Corrosion Resistance Test
56	S-85	Face Mask, Disposable	Piece	A	Physical
				1	Fabric
				2	No. of ply / construction
				3	Sealing of layers
				4	Size
				5	Colour
				6	Length of Strings
57	S-86	Surgical Cap, Disposable	Piece	A	Physical
				1	Fabric
				2	No. of ply / construction
				3	Sealing of layers
				4	Size
				5	Colour
				6	Length of Strings
58	S-87	Foldable Intra Ocular lense	Each	A	Physical
		with injector	Piece	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
					Dioptric power
					Resolution Efficiency Test MTF(modulation transfer function) test
				D	Chemical
				В	
				<u> </u>	ETO Residual Test
				C	Biological
				2	Sterility test Bacterial Endoto xins Test
59	S-88	Standard PMMA Intra Ocular	Each	A	Physical
39	3-00	Lenses	Piece	1	Description
				2	Mechanical tests (Compression force, Axial
				2	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
					Dioptric power
					MTF test
					Resolution Efficiency Test
				В	Chemical
					ETO Residual Test
				С	Biological
				1	Sterility test
				2	Pyrogen / Bacterial Endotoxins Test
60	S-89	Disposable Sterile Surgical	Pair	A	Physical
		Rubber Gloves Size 8 Inches Should Conforms to IS 13422		1	Dimension
		5110 414 CO1110 1112 CO 12 12 12 1 22		2	Thickness
				3	Cuff
				4	Tensile Strength (Mpa) (Before Ageing)
				5	Tensile Strength (Mpa) (After Ageing)
				6	Elongation at break (%) (Before Ageing)
				7	Elongation at break (%) (After Ageing)
		İ	1	i	
				8	Stress at 500% (Mpa) (Before Ageing)

				В	Biological Test
				1	Sterility
61	S-90	Rubber examination gloves	Dispenser	1	Dimension (Length, width)
		made of natural rubber latex.	Boxof	2	Thickness
		Non-sterile, Ambidextous, AQL 1.5 Micro Textured	100 Gloves	3	Tensile Strength (Mpa) (Before Ageing)
		Powdered with absorbable	Gioves	4	Tensile Strength (Mpa) (After Ageing)
		dusting powder USP.		5	Elongation at break (%) (Before Ageing)
		Should Conform to IS 15354			
				6	Elongation at break (%) (After Ageing)
				7	Stress at 500% (Mpa) (Before Ageing)
				8	Water tightness
62	S-91	Pressure Monitoring Line /	Each piece	A	Physical
		High Pressure Extension Line	in Blister Pack	1	Description
			rack	2	Transparency
				3	Particulate Contamination
				4	Components
				5	Leakage
				6	Tensile strength
				В	Chemical
				1	Appearance of extract
				2	Acidity or Alkalinity
				3	UV abs of extract
				4	Buffering capacity
				5	Reducing (Oxidizable)Substance
				6	Metalions
				7	Non Volatile Residue
				В	Biological
				1	Sterility
				2	Toxicity
				3	Pyrogen / Bacterial Endotoxins Test
63	S-92	Urine Collecting Bag for new born / Paediatric urine	Each piece	A	Physical
		collecting Bag		1	Description
				2	Components
				3	Leakage
				В	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
		Dom) - Ansizes		1	Description
				2	Dimensions
				3	Components

				4	Length
				5	Integrity
				В	Biological Test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
				3	Toxicity
65	S-94	Umbilical Cord Clamp	Each piece	(A)	Physical
		1	1	1	Description
				2	Components
				3	Particulate Matter
				B.	Biological Test
				1	Sterility
66	S-95	Absorbable Regenerated	Each piece	A	Physical
		Cellulose Sheet net size 2"X3"		1	Dimensions (Length, width)
		with surgical sponze		2	Absorbablity
				В	Chemical test
				1	Carbo xy lic acid content test
				С	Biological Test
				1	Sterility
				2	Microbial examination test
67	S-96	Close wound Drainage Device	Each piece	A	Physical
		under negative pressure · Closed wound suction unit		a	Container
		Catheter 16FG, 18FG		1	Capacity
		,		2	Negative Pressure
				b	Connecting Tube
				1	O.D. of Tube
				2	Length of Tube
				С	Perforated Tube
				1	O.D. of Tube
				2	Length of Tube
				3	Quality of Perforation & No. of Eyes
				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
				3 B	Leakage Test Chemical Test

				С	Biological Test
				1	Sterility
68	S-97	T – Tube for Common Bile	Each piece	A	Physical
		Duct Drainage		1	Description
				2	Dimensions
				3	Performance
				В	Chemical test
				С	Biological Test
				1	Sterility
				2	Pyrogen / Bacterial Endotoxins Test
69	S-98	Bone Cement with antibiotics	40 gm	A	Physical
		fast & slow setting	Pack	1	Description
				2	Identification
				3	Weight
				4	Setting Time
				В	Chemical test
				С	Biological Test
70	S-	Sanitary Napkin, Beltless	6 napkins	1	Description
	99(a)	IS 5405	per pack	2	Dimensions
				3	Core Length
				4	Width
				5	Thickness
				6	Weight
				7	pH
				8	Absorbency
				9	Packing and Labelling
71	S-	Sanitary Napkin, Belt-type	6 napkins	1	Description
	99(b)	IS 5405	per pack	2	Dimensions
				3	Core Length
				4	Width
				5	Thickness
				6	Weight
				7	pН
				8	Absorbency
				9	Packing and Labelling
72		Sutures (Sterilized Surgical		A	Physical
		Needled Sutures) USP / BP		1	Description
				2	Length
				3	Diameter
				4	Tensile Strength (for USP); Minimum Breaking Load (for BP)
				5	Needle Attachment

A Needle description (size, shape, dimension)					6	Tests for Needle
b Flexibility c Sharpness d Smoothness and finish B Chemical Tests 1 Identification test for sumre material 2 Extractable Colour (if suture is dyed) 3 Soluble chromium compounds (only for chromium categul) 4 Anti-bacterial chemical content (only for antibacterial coated sutures) 5 Corosion resistance test for needle C Biological Test 1 Sterility 1 Description 2 Shape and dimensions 3 Length of catheter 4 Valve 5 Ballon Capacity 6 Diameter of Cathater 7 Tensile strength of rubber 8 Balloon Leakage B Chemical test 1 pH of water ox fract 2 Extractable Colour 3 Heavy metals 1 pH of water ox fract 2 Extractable Colour 3 Heavy metals 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH						
C Sharpness						
A						,
Recommendation Base						_
1 Identification test for suture material 2						
2 Extractable Colour (if suture is dyed) 3 Soluble chromiu me ompounds (only for chromiu matagut) 4 Anti-bacterial coated sutures) 5 Corrosion resistance test for needle C Biological Test 1 Sterility A Physical 1 Description 2 Shape and dimensions 3 Length of catheter 4 Valve 5 Ballon Capacity 6 Diameter of Cathater 7 Tensile strength of rubber 8 Balloon Leakage B Chemical test 1 pH of water extract 2 Extractable Colour 3 Heavy metals C Biological Test 1 Sterility 74 S-99(P) Belt-less Sanitary Napkin with wings 6 napkins per pack 7 Corrosion resistance test for needle C Biological Test 1 Description 2 Shape and dimensions 3 Length of catheter 4 Valve 5 Ballon Capacity 6 Diameter of Cathater 7 Tensile strength of rubber 8 Balloon Leakage B Chemical test 1 pH of water extract 2 Extractable Colour 3 Heavy metals C Biological Test 1 Sterility 1 Description 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency						
S-102 Sterile Catheter, single Use, for Urinary Drainage (Foley Baloon Catheter), 2 way, Size 14 Anti-bacterial chemical content (only for antibacterial coated sutures)						
S-102 S-102 Sterile Catheter, single Use, for Urinary Drainage (Foley Baloon Catheter), 2 way, Size 14						
73 S-102 Sterile Catheter, single Use, for Urinary Drainage (Foley Baloon Catheter), 2 way, Size 14 Fiece 74 S-99(P) 75 S-102 Sterile Catheter, single Use, for Urinary Drainage (Foley Baloon Catheter), 2 way, Size 14 76 S-99(P) 77 S-102 Sterile Catheter, single Use, for Urinary Drainage (Foley Baloon Catheter), 2 way, Size 14 8					3	
Table Sample Sa					4	
S-102 Sterile Catheter, single Use, for Urinary Drainage (Foley Baloon Catheter), 2 way, Size 14					5	Corrosion resistance test for needle
S-102 Sterile Catheter, single Use, for Urinary Drainage (Foley Baloon Catheter), 2 way, Size 14					С	Biological Test
Urinary Drainage (Foley Baloon Catheter), 2 way, Size 14 Piece 1					1	Sterility
Baloon Catheter), 2 way, Size 2 Shape and dimensions 3 Length of catheter 4 Valve 5 Ballon Capacity 6 Diameter of Cathater 7 Tensile strength of rubber 8 Balloon Leakage B Chemical test 1 pH of water extract 2 Extractable Colour 3 Heavy metals C Biological Test 1 Sterility 1 Description 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency 1 Photography 1 Photo	73	S-102			A	Physical
14				Piece	1	Description
A					2	Shape and dimensions
S-99(P) Belt-less Sanitary Napkin with wings S-99(P) Belt-less Sanitary Napkin with wings S-99(P) S-99(P					3	Length of catheter
6 Diameter of Cathater 7 Tensile strength of rubber 8 Balloon Leakage B Chemical test 1 pH of water extract 2 Extractable Colour 3 Heavy metals C Biological Test 1 Sterility 1 Description 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency					4	Valve
Tensile strength of rubber					5	Ballon Capacity
8 Balloon Leakage B Chemical test 1 pH of water extract 2 Extractable Colour 3 Heavy metals C Biological Test 1 Sterility 1 Description 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency					6	Diameter of Cathater
B Chemical test 1 pH of water extract 2 Extractable Colour 3 Heavy metals C Biological Test 1 Sterility 1 Description 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency					7	Tensile strength of rubber
THE Second Property of the content o					8	Balloon Leakage
2 Extractable Colour 3 Heavy metals C Biological Test 1 Sterility 1 Description 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency					В	Chemical test
74 S-99(P) Belt-less Sanitary Napkin with wings Belt-less Sanitary Napkin with wings 6 napkins per pack 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency					1	pH of water extract
T4 S-99(P) Belt-less Sanitary Napkin with wings Belt-less Sanitary Napkin with wings 6 napkins per pack 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency					2	Extractable Colour
74 S- 99(P) Belt-less Sanitary Napkin with wings 1 Sterility 1 Description 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency					3	Heavy metals
74 S- 99(P) Belt-less Sanitary Napkin with wings 6 napkins per pack 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency					С	Biological Test
99(P) wings per pack 2 Dimensions 3 Overall Length 4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency					1	Sterility
2 Dimensions	74				1	Description
4 Core Length 5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency		99(P)	wings	per pack	2	Dimensions
5 Width 6 Thickness 7 Weight 8 pH 9 Absorbency					3	Overall Length
6 Thickness 7 Weight 8 pH 9 Absorbency					4	Core Length
7 Weight 8 pH 9 Absorbency					5	Width
8 pH 9 Absorbency					6	Thickness
9 Absorbency					7	Weight
					8	рН
10 Packing and Labelling					9	Absorbency
10 1 acking and Labering					10	Packing and Labelling

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

* The above tests are minimum tests to be performed.