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

# Ministry of Health \& Family Welfare <br> Government of Rajasthan <br> RMSCL <br> "Mukhyamantri Nishulak Dava Yojana" <br> 'D' Block, Swasthya B hawan, Tilak Marg, Jaipur - 302005, India <br> Tel No: 0141-2228066, 2228064, E-mail: edprmsc@gmail.com <br> Ref. No F.02(45)/RMSCLPProc/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.

## RAJASTHAN MEDICAL SERVICES COR PORATION 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:

Pre- bid conference

Date and time for downloading bid document

Date and time of opening of Online technical bids

Cost of the Bid Document : Rs. 2000/-

RISL Processing Fees
: Rs. 1000/-
Bid Security

Last date and time of submission of online bids
28.08.2017 at $\mathbf{1 . 3 0} \mathbf{~ P M}$
:

- Rs. 2000
: F.02(45)/RMSCLProc/LAB EMPANELMENT(S\&S)/NIB-7/2017/265 dated:26.07.017
03.08.2017 at 11:30 A.M. (RMSCL meeting Hall)
: $\quad$ 26.07.2017 from 06.00 PM
28.08.2017 at 2.30 PM


## RAJASTHAN MEDICAL SERVICES COR PORATION 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 $\mathbf{2 7 . 0 8 . 2 0 1 7}$ 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 201415, 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 Anne xure-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, Che micals, 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 rele vant 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, where ver 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. 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.

## 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 a ny 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

1. 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 nume rical 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 analys is 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 furnish the test report shall be eliminated if it is less than half a day. The maximum amount of liquidated damages shall be $10 \%$.
(iv) If, at any time during the continuance of this Agreement, the laboratory has, in the opinion of the Purchaser, delayed in submitting any test report, by the reasons of any riots, mutinies, wars, fire, storm, earthquakes, tempest or other exceptional cause, on a specific request made by the laboratory, the time for submitting test report may be extended by the RMSCL purely at his discretion for such period as may be considered reasonable. No further representation from the laboratory will be entertained on this account.

## 14. CORRECTION OF ARITHMETIC ERRORS:

Provided that a financial bid is substantially responsive, the procuring Entity will correct arithmetical errors during evaluation of Financial Bids on the following basis:
(i) If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail and the total price shall be corrected, unless in the opinion of the Procuring Entity there is an obvious misplacement of the decimal point in the unit price, in which case the total price as quoted shall govern and the unit price shall be corrected;
(ii) If there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected; and.
(iii) If there is a discrepancy between words and figures, the amount in words shall prevail, unless the amount expressed in words is related to an arithmetic error, in which case the amount in figures shall prevail subject to clause (a) and (b) above.

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

## 15. GRIEVANCE REDRESSAL DURING EMPANELMENT PROCESS:

The Designation and address of the First Appellate Authority is 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. COMPLIANCE WITH THE CODE OF INTEGRITY AND NO

## CONFLICT OF INTEREST:

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

## 17. Conflict of interest:-

The bidder participating in a bidding process must not have a Conflict of Interest.
A Conflict of interest is considered to be a situation in which a party has interests that could improperly influence that party's performance of official
duties or responsibilities, contractual obligations, or compliance with applicable laws and regulations.
I. A bidder may be considered to be in Conflict of interest with one or more parties in bidding process if, including but not limited to:
a. Have controlling partners/shareholders in common; or
b. Receive or have received any direct or indirect subsidy from any of them; or
c. Have the same legal representative for purposes of the bid; or
d. Have a relationship with each other, directly or through common third parties, that puts them in a position to have access to information about or influence on the bid of another bidder, or influence the decisions of the Procuring Entity regarding the bidding process; or
e. The bidder participates in more than one bid in a bidding process. Participation by a bidder in more than one $b$ id will result in the disqualification of all $b$ ids 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


нали\%

Total (in words): ₹


Name of the Depositor

For Bank use onily

 Tender Ref. No.



$\mathfrak{b}$ - MTM Muy

ANNEXURE- II
Ref. Clause No. 2 (3), 3(h)

## ANNUAL TURN OVER STATEMENT

The Annual Turnover (for drugs and medicines including Surgical and sutures testing services) of M/s. $\qquad$ for the past three years are given below and certified that the statement is true and correct.

| S.No. | Years | Turnover in Lakhs (Rs) |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1 | $2013-14$ |  |  |  |  |  |  |
| 2 | $2014-15$ | Rs. | Lakhs |  |  |  |  |
| 3 | $2015-16$ | or |  |  |  |  |  |
|  |  |  |  |  | Total |  | Lakhs |
| 4 | $2014-15$ |  | Lakhs |  |  |  |  |
| 5 | $2015-16$ | Rs. |  |  |  |  |  |
| 6 | Total |  |  |  |  |  |  |
| Average turnover per annual |  |  |  |  |  |  |  |

Date:

Seal:

Siganture of Auditor/ Chartered Accountant
(Name in Capital)

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

Name of the Laboratory : $\qquad$

Address: $\qquad$

Types of Samples Analysed No. of Samples Analysed during (2013-14, 2014-15, 2015-2016 or 2014-15, 2015-2016, 2016-2017)

1. Surgicals (Specify item names)
2. Sutures (Specify types)
3. Implants
4. Devices
5. Drugs \& Medicines
6. Others (Specify)

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

# ANNEXURE - IV (a) <br> Ref. Clause No: 3 (j) (a) 

## PERSONNEL IN QC DEPARTM ENT

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

Signature :
Date :

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 | $\begin{aligned} & \text { Date of } \\ & \text { last } \\ & \text { Validation } \end{aligned}$ | Approved for testing of drugs from State licensing Authority since. $\qquad$ |
| :---: | :---: | :---: | :---: | :---: |

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

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

## FACILITIES IN THE MICROBIOLOGICAL SECTION

## I. LIST OF STOCK CULTURES AVAILABLE

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

Signature :

Name of the Lab :

Date :
Official Seal:

# ANNEXURE - IV (d) <br> 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 <br> Ref. Clause No: 3(k)

## DECLARATION FORM

1. I (Name of the Bidder) $\mathrm{S} / \mathrm{O}$ $\qquad$ , Age $\qquad$ , resident of $\qquad$ , am proprietor /Partner/Director having our office at $\qquad$ and the approved drug testing laboratory (Name). $\qquad$ at (Address) $\qquad$ do hereby declare that I have carefully read all the conditions of bid of Rajasthan Medical Services Corporation Ltd., Jaipur, for the bids floated for empanelment of approved drugs testing laboratories for analysis of surgical \& sutures for the year 2017-18 and 2018-19 (ending on 30.06.2019) and shall abide by all the conditions set forth therein.
2. I further declare that I possess valid approval for testing of all the drugs/surgicals \& sutures for which Price Bid have been submitted by me/us in Cover B and permission on Form 37 have been obtained for testing of these items from State Licensing Authority where ever applicable.
3. That the approval to test drugs/surgical \& sutures have been obtained on Form 37 bearing No. $\qquad$ which is valid/renewed up to $\qquad$ .
4. That the Bidder firm is a proprietorship/Partnership/Pvt. Ltd./Ltd. firm and following are the other partners/directors:-
S.No. Name of Partner/Director Age Present \& Permanent Address
5. That our laboratory/Firm/Company does not stand blacklisted /debarred or banned on any ground either by Bid Inviting Authority or Govt. of Rajasthan on the date of bid submission.

Our laboratory/Firm/Company also does not stand blacklisted, debarred or banned on the ground of wrong reporting of test results or on the ground of submission of fake or forged documents or false information / facts, by any State or Central Government or by its central drug procurement agencies, on the date of bid submission for supply of drugs/medicines in India.
6. That $\mathrm{i} / \mathrm{we}$ have carefully read all the conditions of bid in ref. No. F.02(45)/RMSCLProc/LA BEMPANELMENT(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. $1 /$ 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.:-
$\qquad$
$\qquad$
9. E-mail address :-
(Affidavit - Page2)
10. Bank detail for e-Banking :-
Name of account holder $\qquad$
Full name of Bank with Branch $\qquad$
$\mathrm{A} / \mathrm{c}$ no. with full digits $\qquad$
IFSC code $\qquad$

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

## Verification

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

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

ATTESTED BY NOTARY PUBLIC
(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. Schedule L-1 certificate its no. and date of issue
9. (i) NABL Accreditation no. \& date
(ii) Scope of Accreditation
(iii) Its validity.
10. 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)
(2) (Name)

## ANNEXURE -VII <br> Ref: Clause no. 3 (a),7(1)

| S.No. | Code No. | Name of appro ved 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 40 mm Length 76 cm ) | 1/0 | 12 Foils | As per <br> 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 (1/2 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 <br> 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 20 mm 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 30 mm 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 30 mm length $75-90 \mathrm{~cm}$ | 1/0 | 12 Foils | As per Annexure VIII |  |
| 12. | R-12 | Abs orbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polygly colic Acid / Poly (Gly colide-co-L-lactide) 1/2 Cir Tapercut Needle (Heavy) 35-40mm length $\mathbf{7 5 - 9 0}$ cm | 1 | 12 Foils | As per Annexure VIII |  |
| 13. | R-13 | Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin /Polygly colic Acid / Poly (Glycolide-co-L-lactide) $1 / 2$ Cir RB Needle 40 mm 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 25 mm length 90 cm )Undyed | 3/0 | 12 Foils | As per Annexure VIII |  |
| 15. | R-15 | Abs orbable 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. | $\begin{gathered} \text { Code } \\ \text { No. } \end{gathered}$ | Name of appro ved item (s) with specification | Size | Packing Unit | Test Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | (1/2 Cir RB Needle 20 mm length 70 cm ) |  |  |  |  |
| 16. | R-16 | Absorbable Surgical Suture (Synthetic) Sterilised Surgical Needled Suture (Braided) Coated Polyglactin <br> /Polyglycolic Acid / Poly(Glycolide-co-L-lactide ) (1/2 Cir RB needle 40 mm 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 /Polygly colic Acid / Poly(Glycolide-co-L-lactide) <br> ( $1 / 2$ Cir RB Needle 40 mm 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 /Polygly colic Acid / Poly(Glycolide-co-L-lactide) 3/8 Circle Cutting Needle 22 mm 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 16 mm Needle, Suture Length 70 cm | 4/0 | 12 Foils | As per Annexure VIII |  |
| 20. | R-20 | NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK <br> ( $1 / 2$ Cir RB Needle 20 mm , 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 26 mm , 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 45 mm , 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 , 6 mm 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) <br> (3/8 Conventional Cutting Needle 16 mm 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) <br> (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) <br> (3/8 Cir slim blade Cutting Needle 15 mm 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 $\mathbf{4 0 4 5 m m}$ Length $60-70 \mathrm{~cm}$.) | 2/0 | 12 Foils | As per Annexure VIII |  |
| 28. | R-28 | NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE POLYAMIDE MONOFILAMENT BLACK (NYLON) <br> (3/8 Cir R Cutting Needle 45 mm Length 70 cm .) | 1/0 | 12 Foils | As per Annexure VIII |  |


| S.No. | $\begin{aligned} & \hline \text { Code } \\ & \text { No. } \end{aligned}$ | Name of appro ved 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 75 cm ) 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 16 mm needle, Length 90 cm ) | 6/0 | 12 Foils | As per Annexure VIII |  |
| 31. | R-31 | NON ABSORBABLE SURGICAL <br> SUTURE,STERILISED SURGICAL NEEDLED <br> SUTURE MONOFILAMENT POLYPROPYLENE <br> 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 $\mathbf{4 0}-\mathbf{4 5 m m}$ Length $\mathbf{7 5 - 9 0} \mathrm{cm}$ ) | 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 $\mathbf{1 6 - 1 7 m m}$ Length 7090 cm ) | 5/0 | 12 Foils | As per Annexure VIII |  |
| 36. | R-36 | NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE $(1 / 2 \mathrm{Cir}$ Tapercut Double Needle $17 \mathrm{~mm} \quad$ Length $70-90 \mathbf{c m})$ | 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 25 mm , 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 30 mm , 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 17 mm 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 15 mm Length 60 cm ) | 6/0 | 12 Foils | As per Annexure VIII |  |
| 42. | R-42 | NON ABSORBABLE SURGICAL SUTURE, <br> STERILISED SURGICAL NEEDLED SUTURE <br> MONOFILAMENT POLYPROPYLENE BLUE (3/8 Cir | 6/0 | 12 Foils | As per Annexure VIII |  |


| S.No. | Code No. | Name of appro ved 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 25 mm length 45 cm ) | 3/0 | 12 Foils | $\begin{aligned} & \hline \text { As per } \\ & \text { Annexure VIII } \end{aligned}$ |  |
| 45. | R-45 | NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE (1/2 Cir RB Heavy 40 mm , 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 , 8 mm Double Needle, Suture Length of 70 Cm ) | 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 13 mm Double Needle 70 cm ) | 4/0 | 12 Foils | As per Annexure VIII |  |
| 49. | R-49 | NON ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE BLUE <br> ( $1 / 2$ Circle CC 13 mm Needle, Suture Length of 70 cm ) 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 17 mm Suture Length of 90 cm ) 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 25 mm , Suture Length of 75 cm ) 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. | $\begin{aligned} & \hline \text { Code } \\ & \text { No. } \end{aligned}$ | Name of appro ved 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 <br> Braided (Green / Blue) 1/2 Circle Taper cut , 17 mm <br> Double armed Needle, Suture <br> Length of 90cm with pledgets Size 6 X 3 X 1.5 mm | 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 , 25 mm Double armed Needle, Suture Length of 90 cm with pledgets Size 6 X 3 X 1.5 mm | 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 25 mm , Suture Length 90 cm | 3/0 | 12 Foils | As per Annexure VIII |  |
| 58. | R-61 | ABSORBABLE SURGICAL SUTURE, STERILISED SURGICAL NEEDLED SUTURE <br> POLYGLECAPRONE/ Polyglyconate, <br> MONOFILAMENT SUTURES <br> (1/2 Circle Oval RB Needle 26 mm Needle, Suture Length of 70cm) | $\begin{gathered} \hline \text { Size } \\ 2 / 0 \end{gathered}$ | 12 Foils | As per Annexure VIII |  |
| 59. | R-62 | ABSORBABLE SURGICAL SUTURES POLYGLECAPRONE / Polyglyconate, MONOFILAMENT SUTURES (1/2 Circle Oval RB Contrast Needle 26 mm , suture length 70 cm ) | 3/0 | 12 Foils | As per Annexure VIII |  |
| 60. | R-63 | ABSORBABLE SURGICAL SUTURES Monofilament sutures Polyglecaprone /Polyglyconate (1/2 Circle Cutting 16 mm Needle,suture length 70 cm ) | 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 $70-90 \mathrm{~cm}$ ) | 3/0 | 12 Foils | As per Annexure VIII |  |
| 62. | R-65 | Abs orbable Surgical Suture (Synthetic) Sterilised Needled Suture Monofilament Polydioxanone Violet (1/2 Circle Reverse Cutting $40-50 \mathrm{~mm}$ Length $\mathbf{7 0 - 9 0 c m}$ ) | 1 | 12 Foils | As per Annexure VIII |  |
| 63. | R-66 | ABSORBABLE SURGICALSUTURE, STERILISED <br> SURGICAL NEEDLED SUTURE MONOFILAMENT <br> POLYDIOXANONE Violet ( $1 / 2$ Circle RB 31 mm <br> Needle, Length 70 cm ) | 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 30 mm Needle, Length 70 cm ) | 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 40 mm , 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 40 mm , GS needle, suture length 90 cm | 1/0 | 12 Foils | As per Annexure VIII |  |


| S.No. | $\begin{aligned} & \hline \text { Code } \\ & \text { No. } \end{aligned}$ | Name of appro ved 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 30 mm , suture length $90 \mathrm{~cm} /$ | $2 / 0$ | 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 40 mm , 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 $90 \mathrm{~cm} /$ | 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 20 mm , 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) <br> (3/8 Cutting spatulated Edge Needle, Double arm Needle 6 mm , Suture length $30-42 \mathrm{~cm}$ | 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 | $\begin{aligned} & \hline \text { As per } \\ & \text { Annexure VIII } \end{aligned}$ |  |
| 75. | R-78 | NON ABSORBABLE SURGICAL SUTURE, <br> STERILISED SURGICAL NEEDLED SUTURE <br> BLACK BRAIDED SILK WITH NEEDLE Silk (3/8 Cir <br> RB Needle 20 mm , 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 16 mm , 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 19 mm Length 76 cm ) | 4/0 | 12 Foils | As per Annexure VIII |  |

## SURGICAL LIST

| $\begin{gathered} \text { S. } \\ \text { No. } \end{gathered}$ | Code <br> 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 $50 \mathrm{~mm} x$ 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 <br> - Sharp and easy piercing spike suitable for blood bags and standard blood containers <br> - Transparent cylindrical drip chamber with filter.Filter size should be 200+20 micro meter. <br> - 150 cm long smooth kink resistant tubing <br> - Efficient roller clamp to control and adjust the transfusion rate <br> - Should conform to IS 9824(Part 3):1996 | Unit | As per Annexure VIII |  |
| 5. | S-5(a) | Dis posable Sterile Surgical Rubber Gloves Size $6^{1 / 2}$ Inches <br> - Made of natural rubber Latex, powdered, without tear, properly folded in a paper <br> - Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less <br> - Tensile strength as per EN 455-2 <br> - Powder should be non-allergenic <br> - should Conform to IS 13422 <br> - ISI marked / CE certified / FDA approved | Pair | As per Annexure VIII |  |
| 6. | $\begin{gathered} \hline \text { S- } \\ 5(\mathrm{~b}) \end{gathered}$ | Disposable Sterile Surgical Rubber Gloves Size $61 / 2$ Inches <br> - Made of natural rubber Latex, powder free (Polymer /Silicon Coated), without tear, properly folded in a paper <br> - Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less <br> - Tensile strength as per EN 455-2 <br> - should Conform to IS 13422 <br> 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) | Dis pos able Sterile Surgical Rubber Gloves Size 7 Inches <br> - Made of natural rubber Latex, powdered,;without tear, properly folded in a paper <br> - Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less <br> - Tensile strength as per EN 455-2 <br> - Powder should be non-allergenic <br> - should Conform to IS 13422 <br> - ISI marked / CE certified / FDA approved | Pair | As per Annexure VIII |  |
| 8. | $\begin{gathered} \text { S- } \\ 6(\mathrm{~b}) \end{gathered}$ | Disposable Sterile Surgical Rubber Gloves Size 7 Inches <br> - Made of natural rubber Latex, powder free (Polymer /Silicon Coated), without tear, properly folded in a paper <br> - Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less <br> - Tensile strength as per EN 455-2 | Pair | As per Annexure VIII |  |


| S. <br> No. | Code No. | Name of approved item (s) with specification | Packing Unit | Test <br> Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | - should Conform to IS 13422 <br> 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) | Dispos able Sterile Surgical Rubber Gloves Size $71 / 2$ Inches <br> - Made of natural rubber Latex, powdered, without tear, properly folded in a paper <br> - Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less <br> - Tensile strength as per EN 455-2 <br> - Powder should be non-allergenic <br> - should Conform to IS 13422 <br> - ISI marked / CE certified / FDA approved | Pair | As per Annexure VIII |  |
| 10. | $\begin{gathered} \hline \text { S- } \\ 7(\mathrm{~b}) \end{gathered}$ | Dis pos able Sterile Surgical Rubber Gloves Size $71 / 2$ Inches <br> - Made of natural rubber Latex, powder free (Polymer /Silicon Coated), without tear, properly folded in a paper <br> - Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less <br> - Tensile strength as per EN 455-2 <br> - should Conform to IS 13422 <br> ISI marked / CE certified / FDA approved (CE Certification / FDA Approval for item is mandatory for importer firms, that cannot avail IS Standar ds | Pair | As per <br> Annexure <br> VIII |  |
| 11. | S-8(a) | Suction Catheter, Sterile. Size: FG 5 (For use in respiratory tract) <br> - Soft, kink resistant tubing <br> - Rounded open tip with lateral eye <br> - Colour coded univers al funnel connector for safe connection to standard suction equipment <br> - Length 50 cm (min.) <br> - Should conform to IS0 8836:2014 | Each Piece | As per Annexure VIII |  |
| 12. | $\begin{gathered} \mathrm{S}- \\ 8(\mathrm{~b}) \end{gathered}$ | Suction Catheter, Sterile. Size: FG 6 (For use in respiratory tract) <br> - Soft, kink resistant tubing <br> - Rounded open tip with lateral eye <br> - Colour coded univers al funnel connector for safe connection to standard suction equipment <br> - Length 50 cm (min.) <br> - Should conform to IS0 8836:2014 | Each piece | As per Annexure VIII |  |
| 13. | S-8(c) | Suction Catheter, Sterile. Size: FG 8 (For use in respiratory tract) <br> - Soft, kink resistant tubing <br> - Rounded open tip with lateral eye <br> - Colour coded univers al funnel connector for safe connection to standard suction equipment <br> - Length 50 cm (min.) <br> - Should conform to IS0 8836:2014 | Each piece | As per Annexure VIII |  |
| 14. | $\begin{gathered} \mathrm{S}- \\ 8(\mathrm{~d}) \end{gathered}$ | Suction Catheter, Sterile. Size: FG 10 (For use in respiratory tract) <br> - Soft, kink resistant tubing <br> - Rounded open tip with lateral eye <br> - Colour coded univers al funnel connector for safe connection to standard suction equipment <br> - Length 50 cm (min.) <br> - Should conform to IS0 8836:2014 | Each piece | As per Annexure VIII |  |


| $\begin{gathered} \text { S. } \\ \text { No. } \end{gathered}$ | Code No. | Name of approved item (s) with specification | Packing <br> Unit | Test <br> Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
| 15. | S-8(e) | Suction Catheter, Sterile. Size: FG 12 (For use in respiratory tract) <br> - Soft, kink resistant tubing <br> - Rounded open tip with lateral eye <br> - Colour coded univers al funnel connector for safe connection to standard suction equipment <br> - Length 50 cm (min.) <br> - Should conform to IS0 8836:2014 | Each piece | As per Annexure VIII |  |
| 16. | S-8(f) | Suction Catheter, Sterile. Size: FG 14 (For use in respiratory tract) <br> - Soft, kink resistant tubing <br> - Rounded open tip with lateral eye <br> - Colour coded universal funnel connector for safe connection to standard suction equipment <br> - Length 50 cm (min.) <br> - Should conform to IS0 8836:2014 | Each piece | As per Annexure VIII |  |
| 17. | $\begin{gathered} \mathrm{S}- \\ 8(\mathrm{~g}) \end{gathered}$ | Suction Catheter, Sterile. Size: FG 16 (For use in respiratory tract) <br> - Soft, kink resistant tubing <br> - Rounded open tip with lateral eye <br> - Colour coded universal funnel connector for safe connection to standard suction equipment <br> - Length 50 cm (min.) <br> - Should conform to IS0 8836:2014 | Each piece | As per Annexure VIII |  |
| 18. | $\begin{gathered} \mathrm{S}- \\ 8(\mathrm{~h}) \end{gathered}$ | Suction Catheter, Sterile. Size: FG 18 (For use in respiratory tract) <br> - Soft, kink resistant tubing <br> - Rounded open tip with lateral eye <br> - Colour coded univers al funnel connector for safe connection to standard suction equipment <br> - Length 50 cm (min.) <br> - Should conform to IS0 8836:2014 | Each piece | As per Annexure VIII |  |
| 19. | S-8(i) | Suction Catheter, Sterile. Size: FG 20 (For use in respiratory tract) <br> - Soft, kink resistant tubing <br> - Rounded open tip with lateral eye <br> - Colour coded univers al funnel connector for safe connection to standard suction equipment <br> - Length 50 cm (min.) <br> - Should conform to IS0 8836:2014 | Each Piece | As per Annexure VIII |  |
| 20. | S-8(j) | Suction Catheter, Sterile. Size: FG 22 (For use in respiratory tract) <br> - Soft, kink resistant tubing <br> - Rounded open tip with lateral eye <br> - Colour coded univers al funnel connector for safe connection to standard suction equipment <br> - Length 50 cm (min.) <br> - Should conform to IS0 8836:2014 | Each Piece | As per <br> Annexure <br> VIII |  |
| 21. | S-9(a) | Sterile Catheter, Single Use, for Urinary Drainage (Foley <br> Balloon Catheter), 2 Way, Size 8 FG <br> - Made of Silicone elas tomer bonded with Latex <br> - Should have hard plastic valve <br> - Smooth distal end with smooth eyes for atraumatic intubation <br> - Symmetrical foley balloon | Each Piece | As per Annexure VIII |  |


| $\begin{array}{r} \text { S. } \\ \text { No. } \end{array}$ | Code <br> No. | Name of approved item (s) with specification | Packing Unit | Test Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | - Balloon capacity 3-5 ml <br> - Should conform to IS 11497 <br> - Color coding marking to identify size <br> - Length, wall thickness and balloon capacity should be mentioned as per IS 11497. <br> - Specification for B,C,D,E,F,G should be mentioned as per IS 11497 for particular size |  |  |  |
| 22. | $\begin{gathered} \hline \text { S- } \\ 9(\mathrm{~b}) \end{gathered}$ | Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size 10 FG <br> - Made of Silicone elastomer bonded with Latex <br> - Should have hard plastic valve <br> - Smooth distal end with smooth eyes for atraumatic intubation <br> - Symmetrical foley balloon <br> - Balloon capacity 3-5 ml <br> - Should conform to IS 11497 <br> - Color coding marking to identify size <br> - Length, wall thickness and balloon capacity should be mentioned as per IS 11497. <br> - 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, Size 16 FG <br> - Made of Silicone elastomer bonded with Latex <br> - Should have hard plastic valve <br> - Smooth distal end with s mooth eyes for atraumatic intubation <br> - Symmetrical foley balloon <br> - Balloon capacity 30 ml <br> - Should conform to IS 11497 <br> - Color coding marking to identify size <br> - Length, wall thickness and balloon capacity should be mentioned as per IS 11497. <br> - Specification for B,C,D,E,F,G should be mentioned as per IS11497 for particular size | Each Piece | As per Annexure VIII |  |
| 24. | $\begin{gathered} \mathrm{S}- \\ 9(\mathrm{~d}) \end{gathered}$ | Sterile Catheter, Single Use, for Urinary Drainage (Foley Balloon Catheter), 2 Way, Size 18 FG <br> - Made of Silicone elastomer bonded with Latex <br> - Should have hard plastic valve <br> - Smooth distal end with smooth eyes for atraumatic intubation <br> - Symmetrical foley balloon <br> - Balloon capacity $30 \pm 1 \mathrm{ml}$ <br> - Should conform to IS 11497 <br> - Color coding marking to identify size <br> - Length, wall thickness and balloon capacity should be mentioned as per IS 11497. <br> - 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 <br> Balloon Catheter), 2 Way, Size 20 FG <br> - Made of Silicone elas tomer bonded with Latex <br> - Should have hard plastic valve <br> - Smooth distal end with s mooth eyes for atraumatic intubation <br> - Symmetrical foley balloon <br> - Balloon capacity $30 \pm 1 \mathrm{ml}$ | Each piece | As per Annexure VIII |  |


| S. <br> No. | Code <br> No. | Name of approved item (s) with specification |  | Packing <br> Unit | Test <br> Proposed to <br> be carried <br> out |
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| $\begin{gathered} \text { S. } \\ \text { No. } \end{gathered}$ | Code No. | Name of approved item (s) with s pecification | Packing Unit | Test Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
| 31. | S-11 | Sterile Disposable Perfusion Set with Airway and Needle (Adult Use) <br> - For gravity feed only <br> - Sharp and easy piercing spike with air vent <br> - Transparent and flexible drip chamber <br> - 150 cm long smooth kink resistant tubing <br> - Self sealing latex bulb which will also act as an port for extra medication <br> - Efficient roller clamp to control and adjust the fluid rate <br> - 21 Gneedle <br> - 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) <br> - Burette type measured volume chamber of 100 ml <br> - Drop size of approx 60 drops per ml <br> - Injection port,latexfree, for intermittent medication. <br> - Floating auto shut off valve (latex free) in burette. <br> - Soft and kink resistant PVC tubing. <br> - Roller controller for flow control <br> - Tube length 150 cm <br> - 23Gneedle <br> - Should conform to ISO 8536-5 | Unit | As per Annexure VIII |  |
| 33. | S-13 | Sterile Disposable Infusion Set with Microdrip (I.V.) <br> - Microdrip Infusion set with drop size reduced to approx 60 drops per ml <br> - Sharp and eas y piercing spike <br> - Transparent and flexible drip chamber <br> - 150 cm long smooth kink resistant tubing <br> - Efficient roller clamp to control and adjust the fluid rate <br> - 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 <br> (a) | Sterile Disposable (Single Use) Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock. Size 16G <br> - Should be packed in transparent, single blister pack. <br> - Should conform to IS 10555 standard | Each Piece | As per Annexure VIII |  |
| 36. | S-15 <br> (b) | Sterile Disposable (Single Use Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock. ) Size 18G <br> - Should be packed in transparent, single blister pack. <br> - Should conform to IS 10555 standard | Each Piece | As per Annexure VIII |  |
| 37. | S-15 <br> (c) | Sterile Disposable (Single Use) Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock. Size 20G <br> - Should be packed in transparent, single blister pack. <br> - Should conform to IS 10555 standard | Each Piece | As per <br> Annexure <br> VIII |  |
| 38. | S-15 <br> (d) | Sterile Dis posable (Single Use) Teflon / PTFE I.V. Cannula with integrated 3 Way stop cock. Size 22G <br> - Should be packed in transparent, single blister pack. <br> - Should conform to IS 10555 standard | Each Piece | As per Annexure VIII |  |
| 39. | S-15 <br> (e) | Sterile Dis posable (Single Use) Teflon/ PTFE I.V. Cannula without port. Size 24G <br> - Suitable for paediatric \& neonatal use <br> - Should be packed in transparent, single blister pack. <br> - Should conform to IS 10555 standard | Each Piece | As per Annexure VIII |  |


| $\begin{gathered} \text { S. } \\ \text { No. } \end{gathered}$ | Code <br> No. | Name of approved item (s) with specification | Packing Unit | Test Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
| 40. | S-16 | Mucus Extractor Sterile <br> - Clear transparent container <br> - Antibacterial filter <br> - Soft, kink resistant PVC tubing <br> - Tube Size 10 FG , Length 40 cm (min.) <br> - Capacity 25 ml | Unit | As per Annexure VIII |  |
| 41. | $\begin{aligned} & \hline \text { S- } \\ & 17(a) \end{aligned}$ | Nasal Oxygen Cannula (Set), Twin Bore (accessory for compressed air breathing) All Sizes (Adult) <br> - Soft and kink resistant PVC tubing <br> - Multichannel / star lumen to preventing accidental kinking <br> - Twin bores should ensure equal volume of oxygen to both air passages <br> - Connector for easy connection to the oxygen source <br> - Tube length 200 cm | Each Piece | As per Annexure VIII |  |
| 42. | $\begin{aligned} & \hline \text { S- } \\ & 17(b) \end{aligned}$ | Nasal Oxygen Cannula (Set), Twin Bore (accessory for compressed air breathing) All Sizes (Pediatrics) <br> - Soft and kink resistant PVC tubing <br> - Multichannel / star lumen to preventing accidental kinking <br> - Twin bores should ensure equal volume of oxygen to both air passages <br> - Connector for easy connection to the oxygen source <br> - 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 $15 \mathrm{~cm} \mathrm{X} 2.7 \mathrm{mts} /$ 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 10 cm X 2.7 mts / Roll Should conform to Schedule F(II) of Drug and Cosmetic Act 1940 | Unit | As per <br> Annexure VIII |  |
| 48. | S-23 <br> (a) | Ryle's Tube / Nasogastric Tube (P.V.C.) with radio opaque lining. Size: 10 <br> - Soft, kink resistant PVC tubing for atraumatic intubation <br> - Closed distal end should be coned with radio opaque material for accurate intubation <br> - Four lateral eyes for greater efficiency <br> - Radio opaque line <br> - Marking at 50, 60, 70 cm from tip <br> - Colour coded funnel <br> - With luer connector / closure <br> - Length 105 cm | Each Piece | As per Annexure VIII |  |
| 49. | S-23 <br> (b) | Ryle's Tube / Nasogas tric Tube (P.V.C.) with radio opaque lining. Size: 12 <br> - Soft, kink resistant PVC tubing for atraumatic intubation <br> - Closed distal end should be coned with radio opaque material for accurate intubation <br> - Four lateral eyes for greater efficiency | Each Piece | As per Annexure VIII |  |


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


| $\begin{array}{r} \text { S. } \\ \text { No. } \end{array}$ | Code <br> No. | Name of approved item (s) with specification | Packing Unit | Test <br> Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | - Sterile |  |  |  |
| 55. | $\begin{gathered} \mathrm{S}- \\ 25(\mathrm{c}) \end{gathered}$ | Scalp Vein Set (Disposable): Size 22G <br> - Butterfly shaped wings for easy handling and attachment with skin. Colour coded <br> - Needle should be bevelled, siliconised and should ensure atraumatic cannulation <br> - Female luer fitting at one end <br> - Soft, kink resistant, non-toxic, non irritant tube <br> - Sterile | Each Piece | As per Annexure VIII |  |
| 56. | $\begin{gathered} \mathrm{S}- \\ 25(\mathrm{~d}) \end{gathered}$ | Scalp Vein Set (Disposable): Size 24G <br> - Butterfly shaped wings for easy handling and attachment with skin. Colour coded <br> - Needle should be bevelled, siliconised and should ensure atraumatic cannulation <br> - Female luer fitting at one end <br> - Soft, kink resistant, non-toxic, non irritant tube <br> - Sterile | Each Piece | As per Annexure VIII |  |
| 57. | S-26 | Sterile Hypodermic Syringe with Needle attached, 24G, Single Use - 2 ml <br> - Clear transparent chamber <br> - Prominent graduation <br> - Inert material gasket at the piston to minimise friction during movement \& prevent leakage and back flow <br> - Sharp needle ensuring minimum trauma during penetration <br> - Shall conform to IS 12050 <br> - Packing: Needle should be attached with the syringe and packed in unit ribbon pack <br> - The words "DESTROY AFTER SINGLE USE" or equi valent 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 <br> - Clear transparent chamber <br> - Prominent graduation <br> - Inert material gasket at the piston to minimise friction during movement \& prevent leakage and back flow <br> - Sharp needle ensuring minimum trauma during penetration <br> - Shall conform to IS 12050 <br> - Packing: Needle should be attached with the syringe and packed in unit ribbon pack <br> - The words "DESTROY AFTER SINGLE USE" or equi valent 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 <br> - Clear transparent chamber <br> - Prominent graduation <br> - Inert material gasket at the piston to minimise friction during movement \& prevent leakage and back flow <br> - Sharp needle ensuring minimum trauma during penetration <br> - Shall conform to IS 12050 <br> - Packing: Needle should be attached with the syringe and packed in unit ribbon pack <br> - The words "DESTROY AFTER SINGLE USE" or | Unit | As per Annexure VIII |  |


| $\begin{array}{c}\text { S. } \\ \text { No. }\end{array}$ | $\begin{array}{c}\text { Code } \\ \text { No. }\end{array}$ | $\begin{array}{c}\text { Name of approved item (s) with specification }\end{array}$ | $\begin{array}{c}\text { Packing } \\ \text { Unit }\end{array}$ | $\begin{array}{c}\text { Test } \\ \text { Proposed to } \\ \text { be carried } \\ \text { out }\end{array}$ | Remarks |
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| $\begin{gathered} \text { S. } \\ \text { No. } \end{gathered}$ | 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 610 <br> - It should be mentioned whether needle is Pointed orblunt with type of its point. <br> - Type of eye of the needle should be mentioned. <br> - 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 <br> - It should be mentioned whether needle is Pointed orblunt with type of its point. <br> - Type of eye of the needle should be mentioned. <br> - 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 <br> - It should be mentioned whether needle is Pointed or blunt with type of its point. <br> - Type of eye of the needle should be mentioned. <br> - 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 <br> - It should be mentioned whether needle is Pointed orblunt with type of its point. <br> - Type of eye of the needle should be mentioned. <br> - Should conform to IS-9165 | 6 Nos. /Pkt. | As per Annexure VIII |  |
| 71. | S-38 | Suture Needles Curved And Cutting Size 1-5 <br> - It should be mentioned whether needle is Pointed orblunt with type of its point. <br> - Type of eye of the needle should be mentioned. <br> - Should conform to IS-9165 | 6 Nos. /Pkt. | As per <br> Annexure <br> VIII |  |
| 72. | $\begin{gathered} \mathrm{S}- \\ 39(\mathrm{a}) \end{gathered}$ | Sterile Dis posable Spinal Needle for Single Use 22G x $31 / 2$ inch <br> - Clear / transparent hub <br> - Sharp tip which should ensure minimal puncture trauma | Each piece | As per Annexure VIII |  |
| 73. | $\begin{gathered} \mathrm{S}- \\ 39(\mathrm{~b}) \end{gathered}$ | Sterile Dis posable Spinal Needle for Single Use 25G x $31 / 2$ inch <br> - Clear / transparent hub <br> - Sharp tip which should ensure minimal puncture trauma | Each piece | As per Annexure VIII |  |
| 74. | S-40 | Urine Collecting Bag, Dis posable 2000 ml <br> - Transparent sheet <br> - Kink resistant flexible tubing not less than 90 cm in length <br> - should have non-return valve <br> - Top drainage outlet <br> - Graduated bag <br> - Moulded handle for easy handling | Unit | As per Annexure VIII |  |
| 75. | S-41 <br> (a) | Double J Stent, Sterile, Both Ends Open - size 4F, length 16 cm <br> - Radio opaque <br> - Should be of inert material, non- irritant to tissue | Each piece | As per Annexure VIII |  |
| 76. | S-41 <br> (b) | Double J Stent, Sterile, Both Ends Open, size 5F, length 20 cm <br> - Radio opaque <br> - Should be of inert material, non- irritant to tissue | Each piece | As per Annexure VIII |  |
| 77. | S-42 <br> (a) | Double J Stent, Sterile, One End Closed - size 4F, length 16 cm <br> - Radio opaque <br> - Should be of inert material, non- irritant to tissue | Each piece | As per Annexure VIII |  |
| 78. | S-42 <br> (b) | Double J Stent, Sterile, One End Closed, size 5F, length 20 cm <br> - Radio opaque <br> - Should be of inert material, non- irritant to tissue | Each piece | As per Annexure VIII |  |
| 79. | $\begin{gathered} \mathrm{S}- \\ 43(\mathrm{a}) \end{gathered}$ | Endotracheal Tube, Plain - Size 2.5 mm <br> - Transparent | Each piece | As per Annexure VIII |  |


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


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


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


| $\begin{array}{r} \text { S. } \\ \text { No. } \end{array}$ | Code <br> No. | Name of approved item (s) with specification | Packing Unit | Test Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
| 102. | S-45 | Tracheostomy Tube (PVC), Plain, Sterile, Single Use - All Sizes <br> - Soft flexible flange at for easy fixation <br> - 15 mm connector at terminal end which can be rotated in 360 degree direction <br> - Non-irritant <br> - Radio-opaque line | Each Piece | As per Annexure VIII |  |
| 103. | S-46 | Tracheostomy Tube (PVC), Cuffed, Sterile, Single Use - All Sizes <br> - Soft flexible flange at for easy fixation <br> - 15 mm connector at terminal end which can be rotated in 360 degree direction <br> - Non-irritant <br> - Radio-opaque line <br> - Balloon with non retum valve | Each Piece | As per Annexure VIII |  |
| 104. | $\begin{gathered} \text { S- } \\ 47(\mathrm{a}) \end{gathered}$ | Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag ( 2000 ml ) (size 24) <br> - Graduated Bag <br> - Should have well fitting cap <br> - Soft drainage catheter 50 cm long, with radio opaque line <br> - Rounded open distal end with smooth atraumatic eyes in catheter <br> - Catheter with markings at 2 cm interval | Each Piece | As per Annexure VIII |  |
| 105. | $\begin{gathered} \mathrm{S}- \\ 47(\mathrm{~b}) \end{gathered}$ | Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag ( 2000 ml ) (size 28) <br> - Graduated Bag <br> - Should have well fitting cap <br> - Soft drainage catheter 50 cm long, with radio opaque line <br> - Rounded open distal end with smooth atraumatic eyes in catheter <br> - Catheter with markings at 2 cm interval | Each Piece | As per Annexure VIII |  |
| 106. | $\begin{gathered} \mathrm{S}- \\ 47(\mathrm{c}) \end{gathered}$ | Abdominal Drain Kit, Sterile, Having drainage catheter and Collection Bag ( 2000 ml ) (size 32) <br> - Graduated Bag <br> - Should have well fitting cap <br> - Soft drainage catheter 50 cm long, with radio opaque line <br> - Rounded open distal end with smooth atraumatic eyes in catheter <br> - Catheter with markings at 2 cm interval | Each Piece | 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 | $2 \mathrm{gm} /$ Packet | As per Annexure VIII |  |


| $\begin{gathered} \text { S. } \\ \text { No. } \end{gathered}$ | Code No. | Name of approved item (s) with s pecification | Packing Unit | Test <br> Proposed to be carried out | Remarks |
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| 112. | S-81 | Temporary Cardiac Pacing Wire (Electrode) Sterile $1 / 2$ Cir, Tapercut, 26 mm ; straight cutting 60 mm ,breakaway | Sachet | As per Annexure VIII |  |
| 113. | S-82 | Skin Graft Knife Blade (Sterile) (dis posable ) <br> 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. | $\begin{gathered} \text { S- } \\ 84(a) \end{gathered}$ | K Wire, length $375 \mathrm{~mm} ; 1 \mathrm{~mm}$ Length of wire should be mentioned with specification. Should conform to IS 8261 | Each Unit | As per Annexure VIII |  |
| 115. | $\begin{gathered} \mathrm{S}- \\ 84(\mathrm{~b}) \end{gathered}$ | K Wire, length $375 \mathrm{~mm} ; 1.6 \mathrm{~mm}$ <br> - Length of wire should be mentioned with specification. <br> - Should conform to IS 8261 | Each Unit | As per Annexure VIII |  |
| 116. | $\begin{gathered} \mathrm{S}- \\ 84(\mathrm{c}) \end{gathered}$ | K Wire, length 375 mm ; size 1.8 mm <br> - Length of wire should be mentioned with specification. <br> Should conform to IS 8261 | Each Unit | As per Annexure VIII |  |
| 117. | S-85 | Face Mask, Disposable <br> - Should be manufactured from non woven poly prop fabric <br> - Should be 3 ply construction <br> - Should have high bacterial filtration efficiency <br> - Should be heat sealed to keep 3 layers together <br> - Standard size $\mathbf{1 7 . 5} \mathbf{x 9} \mathbf{~ c m}$ <br> - Color green/blue <br> - There should be a string each at all four corners, length of string should be 40 cm <br> - Nose clip should be there <br> - No elastic band. | Piece | As per <br> Annexure <br> VIII |  |
| 118. | S-86 <br> (a) | Surgical Cap, Dispos able (For Surgeons) <br> - Should be manufactured from non woven fabric. <br> - Strip for tying the cap stitched on the back for proper grip on the forhead. <br> - Green colour <br> - Ultrasonically stitched <br> - Air permeable/breathable <br> - Should retain skin and hair particle. <br> - Strip for tying the cap | Piece | As per <br> Annexure <br> VIII |  |
| 119. | S-86 <br> (b) | Surgical Cap, Dispos able (For Nurses) <br> - Should be manufactured from non woven fabric <br> - Blue / Green colour <br> - Round upon wearing, with elastic <br> - Air permeable / breathable <br> - Should retain skin and hair particles | Piece | As per Annexure VIII |  |
| 120. | $\begin{gathered} \text { S- } \\ 87(\mathrm{a}) \end{gathered}$ | Foldable Intra Ocular lense with injector (Size +11 D to +17.5 D) <br> Size :6mm optics. $12-13 \mathrm{~mm}$ total diameter <br> 1. Made of foldable Acrylic (Hydrophobic) material <br> 2. Bi-Convex single piece IOL with as pheric optics <br> 3. Size: 6 mm optics. $12-13 \mathrm{~mm}$ total diameter. | Each piece | As per Annexure VIII |  |


| $\begin{array}{r} \text { S. } \\ \text { No. } \end{array}$ | Code <br> No. | Name of approved item (s) with specification | Packing Unit | Test <br> Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | 4. Modified C loop haptic/plate haptics ( <br> 5. IOL should have UV blocking capability <br> 6. IOL should have $360^{\circ}$ square edge.. <br> 7. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision <br> 8. Diopters -+11 D to +17.5 D at 0.5 D step. <br> 9. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. |  |  |  |
| 121. | $\begin{gathered} \mathrm{S}- \\ 87(\mathrm{~b}) \end{gathered}$ | Foldable Intra Ocular lense with injector (Size + 18 D to + 24 D ) Size: 6 mm optics. $12-13 \mathrm{~mm}$ total diameter <br> 1. Made of foldable Acrylic (Hydrophobic) material <br> 2. Bi-Convex single piece IOL with as pheric optics <br> 3. Size: 6 mm optics. $12-13 \mathrm{~mm}$ total diameter. <br> 4. Modified C loop haptic/plate haptics <br> 5. IOL should have UV blocking capability <br> 6. IOL should have $360^{\circ}$ square edge.. <br> 7. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision <br> 8. Diopters -+18 D to +24 D at 0.5 D step. <br> 9. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. | Each piece | As per Annexure VIII |  |
| 122. | $\begin{gathered} \mathrm{S}- \\ 87(\mathrm{c}) \end{gathered}$ | Foldable Intra Ocular lense with injector (Size +24.5 D to +28.5 D ) <br> Size :6mm optics. $12-13 \mathrm{~mm}$ total diameter <br> 1. Made of foldable Acrylic (Hydrophobic) material <br> 2. Bi-Convex single piece IOL with as pheric optics <br> 3. Size: 6 mm optics. $12-13 \mathrm{~mm}$ total diameter. <br> 4. Modified C loop haptic/plate haptics <br> 5. IOL should have UV blocking capability <br> 6. IOL should have $360^{\circ}$ square edge.. <br> 7. foldable and insertion by injector with disposable cartridge insertable by a sub 2.8 mm incision size or smaller incision <br> 8. Diopters -+24.5 D to +28.5 D at 0.5 D step. <br> 9. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. | Each piece | As per Annexure VIII |  |
| 123. | $\begin{gathered} \text { S- } \\ 88(\mathrm{a}) \end{gathered}$ | Standard PMMA Intra Ocular Lenses (Size + 11 D to +17.5 D) <br> -6mm optic size $12.5-13.0 \mathrm{~mm}$ total diameter, Biconvex <br> 1. PMMA optics and haptics single piece with hole <br> 2. 6 mm optic size 12.5 to 13 mm total diameter, Biconvex <br> 3. IOL haptics - modified C shaped with $5^{\circ}-10^{\circ}$ anterior angulation. <br> 4. Should have $360^{\circ}$ square edges. <br> 5. IOL should have UV blocking capability <br> 6 . Diopters -+11 D to +17.5 D at 0.5 D step. <br> 7. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. | Each piece) | As per Annexure VIII |  |
| 124. | $\begin{gathered} S- \\ 88(b) \end{gathered}$ | Standard PMMA Intra Ocular Lenses (Size + 18 D to + 24 D ) <br> -6mm optic size 12.5-13.0 mm total diameter, Biconvex <br> 1. PMMA optics and haptics single piece with hole <br> 2. 6 mm optic size 12.5 to 13 mm total diameter, Biconvex <br> 3. IOL haptics - modified C shaped with $5^{\circ}-10^{\circ}$ anterior angulation. <br> 4. Should have $360^{\circ}$ square edges. <br> 5. IOL should have UV blocking capability <br> 6. Diopters -+18 D to +24 D at 0.5 D step. <br> 7. Supplying unit should be ISO accredited and IOL should be | Each piece | As per Annexure VIII |  |


| $\begin{gathered} \mathrm{S} . \\ \text { No. } \end{gathered}$ | Code No. | Name of approved item (s) with s pecification | Packing Unit | Test Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | CE/US FDA certified. |  |  |  |
| 125. | $\begin{gathered} \mathrm{S}- \\ 88(\mathrm{c}) \end{gathered}$ | Standard PMMA Intra Ocular Lenses (Size + 24.5 D to + 28.5 D ) <br> 6mm optic size 12.5-13.0 mm total diameter, Biconvex <br> 1. PMMA optics and haptics single piece with hole <br> 2. 6 mm optic size 12.5 to 13 mm total diameter, Bioconvex <br> 3. IOL haptics - modified C shaped with $5^{\circ}-10^{\circ}$ anterior angulation. <br> 4. Should have $360^{\circ}$ square edges. <br> 5. IOL should have UV blocking capability <br> 6. Diopters -+24.5 D to +28.5 D at 0.5 D step. <br> 7. Supplying unit should be ISO accredited and IOL should be CE/US FDA certified. | Each piece | As per Annexure VIII |  |
| 126. | S-89 | Disposable Sterile Surgical Rubber Gloves Size 8 Inches <br> - made of natural rubber latex- powder free latex free, without tear,properly folded in a paper <br> - Should Conform to IS 13422 <br> - ISI marked/CE certified/FDA approved <br> - Colour code marking to designate size | Pair | As per Annexure VIII |  |
| 127. | $\begin{gathered} \mathrm{S}- \\ 90(\mathrm{a}) \end{gathered}$ | Rubber examination gloves made of natural rubber latex. Nonsterile, 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. | $\begin{gathered} \mathrm{S}-90 \\ \text { (b) } \end{gathered}$ | Rubber examination gloves made of natural rubber latex. Nonsterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Small should conform to IS 15354 | Dispenser Box of 100 Gloves | $\begin{aligned} & \text { As per } \\ & \text { Annexure } \\ & \text { VIII } \end{aligned}$ |  |
| 129. | $\begin{gathered} \mathrm{S}-90 \\ \text { (c) } \end{gathered}$ | Rubber examination gloves made of natural rubber latex. Nonsterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Medium should conform to IS 15354 | $\begin{gathered} \text { Dispenser } \\ \text { Box of } 100 \\ \text { Gloves } \end{gathered}$ | $\begin{aligned} & \text { As per } \\ & \text { Annexure } \\ & \text { VIII } \end{aligned}$ |  |
| 130. | $\overline{S-90}$ <br> (d) | Rubber examination gloves made of natural rubber latex. Nonsterile, Ambidextous, AQL 1.5 Micro Textured Powdered with absorbable dusting powder USP. Large should conform to IS 15354 | $\begin{gathered} \text { Dispenser } \\ \text { Box of } 100 \\ \text { Gloves } \end{gathered}$ | $\begin{aligned} & \text { As per } \\ & \text { Annexure } \\ & \text { VIII } \end{aligned}$ |  |
| 131. | S-91 | Pressure Monitoring Line / High Pressure Extension Line <br> - Suitable for high pressure monitoring and for connection between syringe infusion pump and patient <br> - 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. <br> - Pressure upto 800 psi <br> - Length 200 cm <br> - Sterile | Each piece in Blister Pack | As per <br> Annexure VIII |  |
| 132. | S-92 | Urine Collecting Bag for new born / Paediatric urine collecting Bag <br> - Should have suitability for both male and female patients <br> - Should be provided with adhesive for fixation and good grip with minimal risk of allergy and injury <br> - Capacity 100 ml <br> - Sterile | Each piece | As per Annexure VIII |  |


| $\begin{gathered} \text { S. } \\ \text { No. } \end{gathered}$ | Code No. | Name of approved item (s) with specification | Packing <br> Unit | Test <br> Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
| 133. | S-93 | Umbilical Catheter (for New Born) All sizes <br> - Radio opaque line <br> - With female fle xible mount <br> - Colour coded connector <br> - Open tip should be soft, rounded, atraumatic <br> - Length 40 cm | Each Piece | As per Annexure VIII |  |
| 134. | S-94 | Umbilical Cord Clamp <br> - Suitable for clamping umbilical cord of new born <br> - Security lock to prevent accidental opening after clamping <br> - Grooved clamping area | Each piece | As per Annexure VIII |  |
| 135. | S-95 | Absorbable Oxidized Regenerated Cellulose net size 2"x 3" with surgical sponge <br> Topical Absorbable Haemostatic Bactericidal Property | Each piece | As per <br> Annexure <br> VIII |  |
| 136. | $\begin{gathered} \hline \text { S- } \\ 96 \mathrm{~A} \end{gathered}$ | Close wound Drainage Device under negative pressure (Closed Wound Suction Unit) <br> - Option to use one or two catheters simultaneously <br> - Bellow chamber with capacity 800 ml <br> - Bellow unit with connector <br> - Graduated Bellow <br> - Connecting tube with clamp and " Y "connector <br> - Curved needle / trocar with catheter <br> - Multiperforated catheter / Radon drain with radio opaque line <br> - Catheter 16 FG | Each Piece( | As per Annexure VIII |  |
| 137. | $\begin{gathered} \text { S- } \\ 96 \mathrm{~B} \end{gathered}$ | Close wound Drainage Device under negative pressure (Closed Wound Suction Unit) <br> - Option to use one or two catheters simultaneously <br> - Bellow chamber with capacity 800 ml <br> - Bellow unit with connector <br> - Graduated Bellow <br> - Connecting tube with clamp and "Y"connector <br> - Curved needle / trocar with catheter <br> - Multiperforated catheter / Radon drain with radio opaque line <br> - Catheter 18 FG | Each Piece | As per Annexure VIII |  |
| 138. | S-97 | T - Tube for Common Bile Duct Drainage <br> - Kehr's T Tube made from medical grade PVC, and siliconized <br> - Smooth, kink resistant <br> - Radio opaque line throughout the length <br> - Sterile <br> - Length $20 \times 60 \mathrm{~cm}$ <br> - Size 10 to 18 FG | Each piece | As per Annexure VIII |  |
| 139. | S-98 | Bone cement with antibiotics, fast and slow setting | $\begin{aligned} & \hline 40 \mathrm{GM} \\ & \text { PACK } \end{aligned}$ | As per Annexure VIII |  |
|  |  | General Specification for S-99(a) and S-99(b) <br> Sanitary Napkins (for Menstrual Hygiene) Specifications:- <br> - Sanitary Napkin consists of an outer covering provided with sufficient number of channels for leak protection and an absorbent filler material. <br> - 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 |  |


| $\begin{array}{r} \text { S. } \\ \text { No. } \end{array}$ | Code <br> No. | Name of approved item (s) with specification | Packing Unit | Test <br> Proposed to be carried out | Remarks |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | odourless. <br> - The material used in fabrication shall be non allergenic. <br> - $\quad$ Shall be free from acids and alkali. <br> - Each primary package shall contain 6 napkins in a polyethylene bag of good quality which should conform to size of product and sealed properly. <br> - Both upper and lower sheets shall be white in colour. <br> - Shall conform to IS 5405. <br> - Type of material and size should be mentioned as per IS 5405 <br> - Instruction for usage should be mentioned on every packet. |  |  |  |
| 140. | $\begin{gathered} \mathrm{S}- \\ 99(\mathrm{a}) \end{gathered}$ |  | 6 napkins per pack | As per Annexure VIII |  |
| 141. | $\begin{aligned} & \hline \text { S- } \\ & 99(\mathrm{~b}) \end{aligned}$ | Sanitary Napkin, Belttype <br> 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. <br> 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 <br> 3. Size - The size of absorbent section / complete sanitary napkin shall be as follows: (in mm ) <br> Absorbent section <br> 4. Weight : $\mathbf{1 2 + \_ 3} \mathbf{~ g m}$ <br> 5. Pack - Six napkins in a pack. <br> 6. Elastic Belt with loops shall be provided in each pack. <br> 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. <br> No. | Code <br> No. | Name of approved item (s) with specification | Packing <br> Unit | Test <br> Proposed to <br> be carried <br> out | Remarks |
| :---: | :---: | :--- | :--- | :--- | :--- |
| 142. | S- <br> $99(P)$ | Belt-less Sanitary Napkin with wings <br> 1. Covering -Good Quality knitted sleeve or non woven fabric of <br> rash free,non irritant and soft to touch material which has <br> sufficient porsity to permit the assembled napkin to meet <br> absorbency requirements.The napkins shall have a non absorbent <br> barrier on one side with adhesive covered by a differently <br> identifiable paper | 6napkins per <br> pack | As per <br> Annexure <br> VIII |  |

## ANNEXURE VIII

Clause 2(8)

| Surgicals Items - Testing Parameters |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: |
| $\begin{aligned} & \text { Sr. } \\ & \text { No } \end{aligned}$ | Code No. | Item Description | Unit |  | Test proposed to be carried out (Standard) |
| 1 | S-1 | Absorbable Ge latin Sponge IP 66, Size $80+-10 \mathrm{~mm} \times 50 \mathrm{~mm}$ x 10 mm . Should be sterlised | Piece | A | Physical |
|  |  |  |  | 1 | Description |
|  |  |  |  | B | Chemical |
|  |  |  |  | 1 | Water Absorbance |
|  |  |  |  | 2 | Density |
|  |  |  |  | 3 | Formaldehyde |
|  |  |  |  | 4 | Total Nitrogen |
|  |  |  |  | 5 | Ash |
|  |  |  |  | 6 | Water |
|  |  |  |  | C | Biological Test |
|  |  |  |  | 1 | Sterility |
|  |  |  |  | 2 | Pyrogen / Bacterial Endoto xins Test |
| 2 | S-2 | Absorbent Cotton Wool IP 500 gm | Packet | A | Physical |
|  |  |  |  | 1 | Description |
|  |  |  |  | 2 | Colouring Matter |
|  |  |  |  | B | Chemical test |
|  |  |  |  | 1 | Identification A By Microscopic |
|  |  |  |  | 2 | Identification B By Chemically |
|  |  |  |  | 3 | Identification C By Che mically |
|  |  |  |  | 4 | Acidity or Alkalin ity |
|  |  |  |  | 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 Dry ing |
| 3 | S-3 | Asepto Syringe with Transparent Bulb, Sterile, 60 ml | Piece | A | Physical |
|  |  |  |  |  | Description |
|  |  |  |  |  | Components |
|  |  |  |  |  | Freedom fromextraneous Matter |
|  |  |  |  |  | Leakage |
|  |  |  |  |  | Capacity |


|  |  |  |  | Transparency |
| :--- | :--- | :--- | :--- | :--- | :--- |


|  |  |  |  | 1 | Sterility |
| :---: | :--- | :--- | :--- | :--- | :--- |
| S-6 | Disposable Sterile Surg ical <br> Rubber Gloves Size 7 Inches <br> IS 13422 | Pair | A | Physical |  |
|  |  |  |  | 1 | Dimension |


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|  |  |  |  | 9 | Injection site |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  | 10 | Male Fitting |
|  |  |  |  | 11 | Test for efficiency of flu id filter |
|  |  |  |  | 12 | Test of Injection site |
|  |  |  |  | 13 | Particulate contamination |
|  |  |  |  | B | Chemical test |
|  |  |  |  | 1 | Acidity or Alkalinity |
|  |  |  |  | 2 | UV Absorbency of ext ract |
|  |  |  |  | 3 | Reducing (Oxidizab le)Substance |
|  |  |  |  | 4 | Heavy Metal Ions |
|  |  |  |  | 5 | Residue on evaporation |
|  |  |  |  | C | Biological Test |
|  |  |  |  | 1 | Sterility Test |
|  |  |  |  | 2 | Pyrogen / Bacterial Endoto xins Test |
|  |  |  |  | 3 | Toxic ity Test |
| 14 | S-14 | Insulin syringe ( 40 units) with | Unit | A | Physical |
|  |  | (fixed) 30 G needle |  | 1 | Description |
|  |  | IS 12227 |  | 2 | Dimensions |
|  |  |  |  | 3 | Components |
|  |  |  |  | 4 | Freedom fromextraneous Matter |
|  |  |  |  | 5 | Properties of needle |
|  |  |  |  | 6 | Fit of piston in barrel (Test for force required to operate plunger) |
|  |  |  |  | 7 | Dead space |
|  |  |  |  | 8 | Leakage at needle |
|  |  |  |  | 9 | Leakage past piston |
|  |  |  |  | 10 | Markings and Graduations |
|  |  |  |  | B | Chemical Test |
|  |  |  |  | 1 | Limit for Ext ractable Metals |
|  |  |  |  | 2 | Limit for Acid ity or Alkalinity (pH) |
|  |  |  |  | C | Biological Test |
|  |  |  |  | 1 | Sterility |
|  |  |  |  | 2 | Pyrogen / Bacterial Endoto xins Test |
|  |  |  |  | 3 | Toxic ity |
| 15 | S-15 | Sterile Disposable (Single Use) | Each | A | Physical |
|  |  | Teflon/ PTFE I.V. Cannula | Piece | 1 | Description |
|  |  | with integrated 3 W ay stop cock. Size 16G, 18G, 20G, 22G IS 10555 |  | 2 | Dimensions (outside diameter, effective length) |
|  |  | And |  | 3 | Surface (free from extraneous matter) |
|  |  | Sterile Disposable (Single Use) Teflon/PTFE IV Cannula |  | 4 | Force at Break |
|  |  | without port 24G IS 10555 |  | 5 | Freedom from liquid leakage under pressure |


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| 19 | S-19 | Paper Adhesive Plaster 2" X 9.0 mts (with cutter) Non woven adhesive tape | Unit | A | Physical |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  | 1 | Description |
|  |  |  |  | 2 | Dimension (Length, width) |
|  |  |  |  | 3 | Tensile strength |
|  |  |  |  | 4 | Adhesive strength |
| 20 | S-20 | Paper Adhesive Plaster 3" X 9.0 mts (with cutter) Non woven adhesive tape | Unit | A | Physical |
|  |  |  |  | 1 | Description |
|  |  |  |  | 2 | Dimension (Length, width) |
|  |  |  |  | 3 | Tensile strength |
|  |  |  |  | 4 | Adhesive strength |
| 21 | S-21 | Plaster of Paris Bandages 15 cm X 2.7mts / Roll | Unit | A | Physical |
|  |  |  |  | 1 | Description |
|  |  |  |  | 2 | Weight per unit area of Bandage \& fabric |
|  |  |  |  | B | Chemical Test |
|  |  |  |  | 1 | Fiber Identification |
|  |  |  |  |  | Identification A (Cotton) |
|  |  |  |  |  | Identification B (Iodinated Zinc Ch loride 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 10 cm X 2.7mts / Roll | Unit | A | Physical |
|  |  |  |  | 1 | Description |
|  |  |  |  | 2 | Weight per unit area of Bandage \& fabric |
|  |  |  |  | B | 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 |


| 23 | S-23 | Ryle's Tube / Nasogastric Tube Size: 10,12 | Each <br> Piece | A | Physical |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  | 1 | Description |
|  |  |  |  | 2 | Components |
|  |  |  |  | 3 | Radio opaque line |
|  |  |  |  | 4 | Markings |
|  |  |  |  | 5 | Funnel luer connector/closure |
|  |  |  |  | 6 | Length |
|  |  |  |  | 7 | Particulate Matter |
|  |  |  |  | 8 | Leakage |
|  |  |  |  | B | Biological Test |
|  |  |  |  | 1 | Sterility |
|  |  |  |  | 2 | Toxic ity |
|  |  |  |  | 3 | Pyrogen / Bacterial Endoto xins Test |
| 24 | S-24 | Ryle's Tube / Nasogastric Tube Size: 14,16,18 | Each Piece | A | Physical |
|  |  |  |  | 1 | Description |
|  |  |  |  | 2 | Components |
|  |  |  |  | 3 | Radio opaque line |
|  |  |  |  | 4 | Markings |
|  |  |  |  | 5 | Funnel luer connector/closure |
|  |  |  |  | 6 | Length |
|  |  |  |  | 7 | Particulate Matter |
|  |  |  |  | 8 | Leakage |
|  |  |  |  | B | Biological Test |
|  |  |  |  | 1 | Sterility |
|  |  |  |  | 2 | Toxic ity |
|  |  |  |  | 3 | Pyrogen / Bacterial Endoto xins Test |
| 25 | S-25 | Scalp Vein Set (Disposable): <br> Size 18G, 20G, 22G,24G |  | A | Physical |
|  |  |  |  | 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 |
|  |  |  |  | B | Chemical |
|  |  |  |  | 1 | Acidity or Alkalin ity |
|  |  |  |  | 2 | Extractable metals |


|  |  |  |  | C |
| :--- | :--- | :--- | :--- | :--- |


|  |  |  |  | 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 | Toxic ity |
| 28 | S-28 | Sterile Hypodermic Syringe | Unit | A | Physical |
|  |  | with Needle attached, 22G, |  | 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 Alkalin ity (pH) |
|  |  |  |  | 2 | Extractable Metals |
|  |  |  |  | C | Biological test |


|  |  |  |  | 1 | Sterility |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  | 2 | Pyrogen / Bacterial Endoto xins Test |
|  |  |  |  | 3 | Toxic ity |
| 29 | S-29 | Sterile Hypodermic Syringe with Needle attached, 22G, Single Use - 20 ml IS 12050 | Unit | A | Physical |
|  |  |  |  | 1 | Description |
|  |  |  |  | 2 | Components |
|  |  |  |  | 3 | Cleanliness |
|  |  |  |  | 4 | Lubrication |
|  |  |  |  | 5 | Tolerance on graduated Capacity |
|  |  |  |  | 6 | 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 Alkalin ity (pH) |
|  |  |  |  | 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 | 100blades /Pkt | 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 <br> Circle Round Body Assorted <br> Size 11-15 <br> Should conform to IS-9165 | 6 Nos. /Pkt. | A | Physical |
|  |  |  |  | 1 | Size, Shape and dimensions |
|  |  |  |  | 2 | Hardness test |


|  |  |  |  |  |  |
| :---: | :---: | :--- | :--- | :--- | :--- |


|  |  | Cutting 1/2 Circle Size 11-15 | Pkt. | 1 | Size, Shape and dimensions |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  | 2 | Hardness test |
|  |  |  |  | 3 | Free from surface defects (Feather edges, burrs, nicks) |
|  |  |  |  | 4 | Fle xibility |
|  |  |  |  | 5 | Sharpness |
|  |  |  |  | B | Chemical Test |
|  |  |  |  | 1 | Corrosion Resistance test |
| 37 | S-37 | Suture Needles Curved And Cutting 1/2 Circle Size 16-20 | 6 Nos. /Pkt. | A | Physical |
|  |  |  |  | 1 | Size, Shape and dimensions |
|  |  |  |  | 2 | Hardness test |
|  |  |  |  | 3 | Free from surface defects (Feather edges, burrs, nicks) |
|  |  |  |  | 4 | Fle xibility |
|  |  |  |  | 5 | Sharpness |
|  |  |  |  | B | Chemical Test |
|  |  |  |  | 1 | Corrosion Resistance test |
| 38 | S-38 | Suture Needles Curved And Cutting Size 1-5 Should conform to IS-9165 | $\begin{aligned} & 6 \text { Nos. } / \\ & \text { Pkt } \end{aligned}$ | A | Physical |
|  |  |  |  | 1 | Size, Shape and dimensions |
|  |  |  |  | 2 | Hardness test |
|  |  |  |  | 3 | Free from surface defects (Feather edges, burrs, nicks) |
|  |  |  |  | 4 | Fle xibility |
|  |  |  |  | 5 | Sharpness |
|  |  |  |  | B | Chemical Test |
|  |  |  |  | 1 | Corrosion Resistance test |
| 39 | S-39 | Sterile Disposable Spinal Needle for Single Use 22G x 3 $1 / 2$ inch \& $25 \mathrm{G} \times 31 / 2$ inch | Each <br> Piece | A | Physical |
|  |  |  |  | 1 | Description |
|  |  |  |  | 2 | Dimensions |
|  |  |  |  | 1 | Leakage Test |
|  |  |  |  | 2 | Sharpness of Needle point |
|  |  |  |  | 3 | Elasticity |
|  |  |  |  | 4 | Reverse Bend Test |
|  |  |  |  | 5 | Stiffness |
|  |  |  |  | 6 | Security of Swag ing |
|  |  |  |  | 7 | Freedom from Foreign Matter |
|  |  |  |  | B | Chemical Test |
|  |  |  |  | 1 | Corrosion Resistance |
|  |  |  |  | C | Biological Test |
|  |  |  |  | 1 | Sterility |
|  |  |  |  | 2 | Toxic ity |
|  |  |  |  | 3 | Pyrogen / Bacterial Endotoxins Test |


| 40 | S-40 | Urine Collecting Bag, Disposable, 2000 ml | Unit | A | Physical |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  | 1 | Description |
|  |  |  |  | 2 | Components |
|  |  |  |  | 3 | Non-return valve |
|  |  |  |  | 4 | Leakage |
|  |  |  |  | B | Biological Test |
|  |  |  |  | 1 | Sterility |
|  |  |  |  | 2 | Pyrogen / Bacterial Endoto xins Test |
|  |  |  |  | 3 | Toxic ity |
| 41 | S-41 | Double J Stent, Sterile, Both Ends Open, size 4F \& 5F, length $16 / 20 \mathrm{~cm}$ | Each <br> Piece | A | Physical |
|  |  |  |  | 1 | Length of Stent |
|  |  |  |  | 2 | O.D. Of Stent |
|  |  |  |  | 3 | I.D. Of Stent |
|  |  |  |  | 4 | Length of pusher |
|  |  |  |  | 5 | OD of guide wire |
|  |  |  |  | 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 |
|  |  |  |  | B | Biological Test |
|  |  |  |  | 1 | Sterility |
|  |  |  |  | 2 | Pyrogen / Bacterial Endoto xins Test |
|  |  |  |  | 3 | Toxic ity |
| 41 | S-42 | Double J Stent, Sterile, One End Closed, size 4F \& 5F, length $16 / 20 \mathrm{~cm}$ | Each Piece | A | Physical |
|  |  |  |  | 1 | Length of Stent |
|  |  |  |  | 2 | O.D. Of Stent |
|  |  |  |  | 3 | I.D. Of Stent |
|  |  |  |  | 4 | Length of pusher |
|  |  |  |  | 5 | OD of guide wire |
|  |  |  |  | 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 |
|  |  |  |  | B | Biological Test |
|  |  |  |  | 1 | Sterility |
|  |  |  |  | 2 | Pyrogen / Bacterial Endoto xins Test |


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


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


|  |  | Tapercut, 26 mm ; Straight cutting 60 mm , breakaway |  | 2 | Visual Testing |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  | 3 | Resistance |
|  |  |  |  | 4 | Strand Length |
|  |  |  |  | 5 | Diameter |
|  |  |  |  | 6 | Needle Testing |
|  |  |  |  | 7 | Tensile Testing |
|  |  |  |  | B | Biological Test |
|  |  |  |  | 1 | Sterility |
| 54 | S-82 | Skin Graft Knife Blade (Sterile, disposable); and Handle (Watson modification of Humby's Knife) | One Pack each | A | Physical |
|  |  |  |  | 1 | Shape and Dimensions |
|  |  |  |  | 2 | Blade hardness |
|  |  |  |  | 3 | Fin ishing |
|  |  |  |  | 4 | Performance test |
|  |  |  |  | B | Chemical Test |
|  |  |  |  | 1 | Corrosion Resistance |
|  |  |  |  | C | Biological Test |
|  |  |  |  | 1 | Sterility |
| 55 | S-84 | K Wire, length $375 \mathrm{~mm} ; 1$ $\mathrm{mm}, 1.6 \mathrm{~mm}, 1.8 \mathrm{~mm}$ IS - 8261 | Each unit | A | Physical |
|  |  |  |  | 1 | Ends |
|  |  |  |  | 2 | Diameter |
|  |  |  |  | 3 | Length |
|  |  |  |  | 4 | Tensile Strength |
|  |  |  |  | B | Chemical Test |
|  |  |  |  | 1 | Corrosion Resistance Test |
| 56 | S-85 | Face Mask, Disposable | Piece | A | Physical |
|  |  |  |  | 1 | Fabric |
|  |  |  |  | 2 | No. of ply / construction |
|  |  |  |  | 3 | 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 with injector | Each Piece | A | Physical |
|  |  |  |  | 1 | Description |


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|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  | Mechanical Tests (Compression force, A xial <br> displacement in compression, Optic <br> decentration, Optic tilt, Angle of contact, <br> Compression force decay, Dynamic fatigue <br> durability, Loop pull strength, Surface and <br> Bulk homogeneity) |


|  |  |  |  | B | Biological Test |
| :--- | :--- | :--- | :--- | :--- | :--- |
|  |  |  |  | 1 | Sterility |


|  |  |  |  |  |
| :--- | :--- | :--- | :--- | :--- |



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[^0]
[^0]:    * The parameters of testing of sutures will be as per the respective pharmacopoeia. * The above tests are minimum tests to be performed.

