Bid Number: GEM/2024/B/47
Dated: 07-06-

Bid Corrigendum

GEM/2024/B/4792508-C17

Following terms and conditions supersede all existing “Buyer added Bid Specific Terms and conditions” given in the document or any previous corrigendum. Prospective bidders are advised to bid as per following Terms and Conditior

Buyer Added Bid Specific Additional Terms and Conditions

1. Buyer Added text based ATC clauses

–

File no:- NEIGR/S&P/R-04/2019-20/Pt V

Approved in 42nd SFC and 69 th Procurement Committee Agenda C-6/69

Scope of work & Document details	
A	**Following mandatory documents must be attached in the bid document as specified, failing which bid will be treated as" non-responsive"**
1	Cost of spares, consumables and accessories not covered under warranty and CMC period shall be offered as percentage value of the system/Unit in the Technical Bid **Additional Doc1 (Requested in ATC)"**
2	Documents with regard to Details compliance statement to be attached At "**Additional Doc 2(Requested in ATC)"**
3	Documents with regard to Original Literature, Product catalogue, technical datasheet from the firm/O.E.M with Highlighting as per the technical specification must attach At **"Additional Doc 3(Requested in ATC)"**
4	Documents with regard to list of Offering/Quoted items mentioning make, model & quantity of each items must be **"Additional Doc 4(Requested in ATC)"**
5	Component wise pricing of all equipment/turnkey/electrical/accessories/HVAC etc **,** must be submitted in the “**Financial Document**” .***Not in technical Bid***

	Any Detail price bid/Component wise pricing should not be attached in the technical bid ,failing which bid will be consider as **“Techno Commercially Non Responsive “**
B	**Warranty and Maintenance**
1	Warranty for 5 years followed by CMC for 5 years including Spares & service for all the items supplied in this particular tender including third-party items and turnkey works .
2	Mandatory 2 PMs / Year with unlimited breakdown calls has to be attended by the Bidder/manufacturer throughout the warranty & CMC period at site.i.e. NEIGRIHMS, SHILLONG.
3	Duly signed Mandatory PM reports has to be submitted periodically, falling which necessary action will be initiated as per term& condition of the tender.
3	E-bidder have to adhere to Government of India, Ministry of Finance, PPD division Public procurement order OM F.No.6/18/2019-PPD dated 23rd july,2020 inserting Rule 144(Xi)in GFR 2017 ,No 1 dated: 23/7/2020 and subsequent Orders No 2 & 3 or as amended from time to time , failing which the bids shall be treated as non-responsive.

–

Buyer Added Bid Specific Terms and Conditions

1. **Generic**

End User Certificate: Wherever Bidders are insisting for End User Certifica from the Buyer, same shall be provided in Buyer’s standard format only.

2. **Generic**

Experience Criteria: The Bidder or its OEM {themselves or through reseller(s
should have regularly, manufactured and supplied same or similar Category
oducts to any Central / State Govt Organization / PSU / Public Listed Compar
or 3 years before the bid opening date. Copies of relevant contracts to be su
mitted along with bid in support of having supplied some quantity during ea
of the year. In case of bunch bids, the primary product having highest value
ould meet this criterion.

3. Generic

IT equipment shall be IPv6 ready from day one.

4. Generic

Installation, Commissioning, Testing, Configuration, Training (As applicable a
per scope of supply) is to be carried out by OEM / OEM Certified resource or
M authorized Reseller.

5. Generic

Upload Manufacturer authorization: Wherever Authorized Distributors a
submitting the bid, Manufacturers Authorization Form (MAF)/Certificate with
EM details such as name, designation, address, e-mail Id and Phone No. requ
ed to be furnished along with the bid.

6. Generic

The successful bidder has to supply all essential accessories required for the
cessful installation and commissioning of the goods supplied. Besides standa
accessories as per normal industry practice, following accessories must be p
of supply and cost should be included in bid price: All the items and accesso
as per Technical Specification.

7. Generic

The Buyer has an existing set up / inventory of similar products. The offered
pplied product must be compatible with existing system. The bidder has to e
re Compatibility of the supplied items or shall have to include in the supply t
ecessary hardware / software to make them compatible at no extra cost to t
uyer. The details of items with which compatibility is required are as under:
he spares Including UPS, PC, battery, Printer, Probes & upgradation of Syste
oftware & third party Software

8. Scope of Supply

Scope of supply (Bid price to include all cost components) : Supply Installati
esting Commissioning of Goods ,Training of operators and providing Statuto
earances required (if any)

9. Turnover

Bidder Turn Over Criteria: The minimum average annual financial turnover o
he bidder during the last three years, ending on 31st March of the previous
ancial year, should be as indicated in the bid document. Documentary evide
e in the form of certified Audited Balance Sheets of relevant periods or a cer
cate from the Chartered Accountant / Cost Accountant indicating the turnov
details for the relevant period shall be uploaded with the bid. In case the da
of constitution / incorporation of the bidder is less than 3 year old, the avera
turnover in respect of the completed financial years after the date of constit
on shall be taken into account for this criteria.

10. Turnover

OEM Turn Over Criteria: The minimum average annual financial turnover of
OEM of the offered product during the last three years, ending on 31st Marc
the previous financial year, should be as indicated in the bid document. Doc
entary evidence in the form of certified Audited Balance Sheets of relevant
ods or a certificate from the Chartered Accountant / Cost Accountant indicat
the turnover details for the relevant period shall be uploaded with the bid. I
se the date of constitution / incorporation of the OEM is less than 3 year old,
e average turnover in respect of the completed financial years after the dat
constitution shall be taken into account for this criteria. In case of bunch bid
he OEM of CATEGORY RELATED TO primary product having highest bid valu
ould meet this criterion.

11. OEM

IMPORTED PRODUCTS: In case of imported products, OEM or Authorized Sell
of OEM should have a registered office in India to provide after sales service
pport in India. The certificate to this effect should be submitted.

12. Purchase Preference (Centre)

As per DPIIT notification at the time of e-tender , bidding or solicitation the b
hall be required to indicate percentage of local content and provide self-cert
tion (by Director/ Company Secretary) and also give details of the location/
which value addition is made". Since the bidder here is not the local supplie
e same was required to be obtained from the "Class-I local supplier /Class
al supplier”

Further the details of Calculations of local content areas under:

Question 1. How to calculate Local Content?

Answer: Para 2 of the PPP-MII Order, 2017 (as amended on 16.09.2020) defi
ocal
content as

Local content’ means the amount of value added in India which shall, unless
erwise
prescribed by the Nodal Ministry, be the total value of the item procured
(excluding net
domestic indirect taxes) minus the value of imported content in the item (in
ng all
customs duties) as a proportion of the total value, in percent.

Mathematically,

Local content = (Sale price - Value of imported content) * 100/ Sale price

Where, “Sale price” means price excluding net domestic indirect taxes and ‘
ue of
imported content” means price of imported content inclusive of all customs
es

Question2. How to calculate Local Content in bids involving supply of multip
ems from single bidder?

Answer: In case of bids requiring supply of multiple items (say “X1”, “X2” ar
3”) by a single bidder, the local content in the bid shall be

Local content = ((Sale price of “X1” - Value of imported content in “X1”) + (
price of “X2” - Value of imported content in “X2”) + (Sale price of “X3” - Val
f imported content in “X3”)) * 100/ (Sale price of “X1” + Sale price of “X2” +
e price of “X3”)

13. Service & Support

Availability of Service Centres: Bidder/OEM must have a Functional Service C
tre in the State of each Consignee's Location in case of carry-in warranty. (N
applicable in case of goods having on-site warranty). If service center is not
eady there at the time of bidding, successful bidder / OEM shall have to est
sh one within 30 days of award of contract. Payment shall be released only a
er submission of documentary evidence of having Functional Service Centre

14. Service & Support

Dedicated /toll Free Telephone No. for Service Support : BIDDER/OEM must h
Dedicated/toll Free Telephone No. for Service Support.

15. Service & Support

Escalation Matrix For Service Support : Bidder/OEM must provide Escalation
trix of Telephone Numbers for Service Support.

16. Certificates

Bidder's offer is liable to be rejected if they don't upload any of the certificat
/ documents sought in the Bid document, ATC and Corrigendum if any.

17. Certificates

The bidder or the OEM of the offered products must have BIS/WHO-GMP/ CD
Indian certification or alternate certification as recognized by Government o
India

18. Certificates

Material Test Certificate Should Be Sent Along with The Supply. The Material
ll Be Checked by Buyer’s Lab & the Results of the Lab will be the Sole Criteri
or Acceptance of the Item.

19. Certificates

The bidder is required to upload, along with the bid, all relevant certificates
ch as BIS licence, type test certificate, approval certificates and other certifi
tes as prescribed in the Product Specification given in the bid document.

20. Certificates

To be eligible for award of contract, Bidder / OEM must possess following Ce
ates / Test Reports on the date of bid opening (to be uploaded with bid): All
quality & electrical safety certificates .

21. Warranty

Bidder / OEM has to give an undertaking that after expiry of warranty period t will provide Comprehensive Maintenance Service for next 5 years for the o red products at the rate not more than 5% of contract price per annum. Buy reserves the right to enter into a CMC agreement with the Successful Bidde OEM after expiry of the Warranty period at above mentioned rate and the pa ment for the CMC charges would be made Biannually after rendering of the MC Services of the relevant CMC period. Performance Security of the succes ul bidder shall be forfeited if it fails to accept the CMC contract when called on by the buyer. CMC would include cost of all the spares Including UPS, PC, attery, Printer, Probes & upgradation of System Software & third party Softw e (Upload the undertaking). The original Performance Security of contract w be returned only after submission and verification of AMC Performance Secu y for 5% of total CMC value valid up to CMC period plus 2 months (if there is o other claim).

22. Warranty

Warranty period of the supplied products shall be 5 years from the date of fi acceptance of goods or after completion of installation, commissioning & tes of goods (if included in the scope of supply), at consignee location. OEM Wa y certificates must be submitted by Successful Bidder at the time of delivery Goods. The seller should guarantee the rectification of goods in case of any k down during the guarantee period. Seller should have well established Installation, Commissioning, Training, Troubleshooting and Maintenance Ser group in INDIA for attending the after sales service. Details of Service Centre ear consignee destinations are to be uploaded along with the bid.

23. Warranty

Over and above the normal Warranty terms as per GeM GTC, the successful er / OEM shall have to provide Comprehensive Warranty during the entire St ard warranty period as per contract. : The comprehensive warranty shall be ering the following scope all the spares Including UPS, PC, battery ,Printer ,P s & upgradation of System Software & third party Software (Upload an unde ng with the bid confirming compliance by the bidder if Bidder is taking onus his compliance. In case OEM is taking onus of this compliance, OEM underta is to be uploaded along with Bidder undertaking)

24. Warranty

Successful bidder will have to ensure that adequate number of dedicated te cal service personals / engineers are designated / deployed for attending to Service Request in a time bound manner and for ensuring Timely Servicing / tification of defects during warranty period, as per Service level agreement

ated in the relevant clause of the bid.

25. Warranty

Timely Servicing / rectification of defects during warranty period: After havir
een notified of the defects / service requirement during warranty period, Sel
as to complete the required Service / Rectification within 3 days' time limit.
e Seller fails to complete service / rectification with defined time limit, a pen
of 0.5% of Unit Price of the product shall be charged as penalty for each wee
delay from the seller. Seller can deposit the penalty with the Buyer directly
the Buyer shall have a right to recover all such penalty amount from the Per
mance Security (PBG). Cumulative Penalty cannot exceed more than 10% of
total contract value after which the Buyer shall have the right to get the ser
/ rectification done from alternate sources at the risk and cost of the Seller b
es forfeiture of PBG. Seller shall be liable to re-imburse the cost of such serv
rectification to the Buyer.

26. Past Project Experience

For fulfilling the experience criteria any one of the following documents may
considered as valid proof for meeting the experience criteria:

a. Purchase Order copy along with Invoice(s) with self-certification by the bi
er that supplies against the invoices have been executed.

b. Execution certificate by client with order value.

c. Any other document in support of order execution like Third Party Inspect
elease note, etc.

27. Past Project Experience

I. SITC AND Operations of CSSD

II. Yearly business turnover of Rs. 2.25 crores or above for last 3 (Three)
ars. Chartered Accountant Certificate should be provided in support of th

III. The tenderer can be a manufacturer or In case the manufacturer does
quote directly, they may authorize their authorized agent as per proform
f Manufacturer authorization form as given in the tender enquiry docume
to quote and enter into a contractual obligation.
The Tenderers quoting as authorized re presentative of the manufacturer
all have three years of experience in the re lated field and should obtain
cuments from principals/manufacturer fulfilling the requirements in respe
of condition mentioned in additional terms, taking full responsibility of te
ical support, service and organizational support

IV. Based on CVC guidelines, the bidder should have Experience of having
cessfully completed /executed SITC AND Operations of CSSD in a hospita
at least one project in major Government/Corporate/International Hospita
ith total gross work order value equivalent to Rs 6 crores (Rupees six cro

s only) (certificate of successful completion and commissioning from the me project should be submitted along with the offer)

OR

At least two projects in major Government/Corporate/International Hospit with total gross work order value equivalent to Rs3.75 crores (Rupees thr crores and seventy-five lakh only) (certificate of successful completion ar commissioning from the same project should be submitted along with the fer)

OR

At least three projects in major Government/Corporate/International Hosp l with tot al gross work order value equivalent to Rs 3 crores (Rupees Thr crores only) (certificate of successful completion and commissioning from e same Project should be submitted along with the offer), during last 7 (s en)years' time, considering the closing date of invitation of b ids of the pr ent tender under consideration or last date of receipt of bids for this tend The value of the executed works shall be brought to the current costing l l by enhancing the actual value of work at simple rate of 7% per annum, culated from the date of completion to last date of receipt of bids for this nder.

V. Example/Clarification: Similar Project means for Supply, Installation and ommissioning of SITC AND Operations of CSSD from major Government/ porate/International Hospital.

VI. In case of authorized agents, manufactures completed /executed projec with documentary evidence may be considered. VII. Wherever Authorized Distributors are submitting the bid, Manufacturers Authorization Form (M /Certificate with OEM details such as name, designation, address, e-mail and Phone No. required to be furnished along with the bid.

28. Forms of EMD and PBG

Bidders can also submit the EMD with Account Payee Demand Draft in favou f NEIGRIHMS EMD SECURITY DEPOSITS payable at MAWDIANGDIANG, SHILLO G-793018, MEGHALAYA . Bidder has to upload scanned copy / proof of the D along with bid and has to ensure delivery of hardcopy to the Buyer within Bi nd date & time / Bid Opening date & time.

29. Forms of EMD and PBG

Bidders can also submit the EMD with Fixed Deposit Receipt made out or ple d in the name of A/C (Name of the Buyer). The bank should certify on it that deposit can be withdrawn only on the demand or with the sanction of the pl e. For release of EMD, the FDR will be released in the favour of the bidder by Buyer after making endorsement on the back of the FDR duly signed and st ed along with covering letter. Bidder has to upload scanned copy/ proof of t DR along with bid and has to ensure delivery of hardcopy to the Buyer within End date & time / Bid Opening date & time.

30. Forms of EMD and PBG

Bidders can also submit the EMD with Banker’s Cheque in favour of NEIGRIH
EMD SECURITY DEPOSITS payable at MAWDIANGDIANG, SHILLONG-793018,
HALAYA . Bidder has to upload scanned copy / proof of the BC along with bid
has to ensure delivery of hardcopy to the Buyer within within Bid End date &
e / Bid Opening date & time.

31. Forms of EMD and PBG

Bidders can also submit the EMD with Payment online through RTGS / intern
banking in Beneficiary name NEIGRIHMS EMD SECURITY DEPOSITS Account
. 30270200000027 IFSC Code BARB0MAWDIA Bank Name BANK OF BARODA
ranch address MAWDIANGDIANG, SHILLONG-793018, MEGHALAYA . Bidder t
ndicate bid number and name of bidding entity in the transaction details fie
at the time of on- line transfer. Bidder has to upload scanned copy / proof of
e Online Payment Transfer along with bid.

32. Forms of EMD and PBG

Successful Bidder can submit the Performance Security in the form of Accou
ayee Demand Draft also (besides PBG which is allowed as per GeM GTC). DD
ould be made in favour of NEIGRIHMS EMD SECURITY DEPOSITS payable at I
DIANGDIANG, SHILLONG-793018, MEGHALAYA . After award of contract, Suc
ful Bidder can upload scanned copy of the DD in place of PBG and has to ens
delivery of hard copy to the original DD to the Buyer within 15 days of award
contract.

33. Forms of EMD and PBG

Successful Bidder can submit the Performance Security in the form of Fixed
osit Receipt also (besides PBG which is allowed as per GeM GTC). FDR shoul
made out or pledged in the name of NEIGRIHMS EMD SECURITY DEPOSITS A
ame of the Seller). The bank should certify on it that the deposit can be with
wn only on the demand or with the sanction of the pledgee. For release of S
ty Deposit, the FDR will be released in favour of bidder by the Buyer after m
g endorsement on the back of the FDR duly signed and stamped along with
ring letter. Successful Bidder has to upload scanned copy of the FDR docume
n place of PBG and has to ensure delivery of hard copy of Original FDR to the
yer within 15 days of award of contract.

34. Forms of EMD and PBG

Successful Bidder can submit the Performance Security in the form of Payme online through RTGS / internet banking also (besides PBG which is allowed a r GeM GTC). On-line payment shall be in Beneficiary name NEIGRIHMS EMD URITY DEPOSITS Account No. 30270200000027 IFSC Code BARB0MAWDIA B Name BANK OF BARODA Branch address MAWDIANGDIANG, SHILLONG-793(MEGHALAYA. Successful Bidder to indicate Contract number and name of Se entity in the transaction details field at the time of on-line transfer. Bidder h upload scanned copy / proof of the Online Payment Transfer in place of PBG in 15 days of award of contract.

29. RELATIONSHIP CERTIFICATE in Bidder,s letter Head with detail Declaratic ust be submiited in the following format"It is certified that I/We, the undersig , do(With Detail name & details)/do not have relationshipwith any of the em ees working at NEIGRIHMS . The above statement is true and is submitted a st the Gem Tender Enquiry_____Dated _____

Date: _____ _____

(Signature) Name of the Company/Firm Seal

30.In case of need of fulfilment of statutory requirement for receipt/Installat Operation of stores /system such as AERB clearance /approval , PC-PNDT, Cl nce from fire department, environmental /Site clearance etc ,the delivery/installation period shall commence from the date of obtaining such rance .

31.In order to ensure provision of services(cmc) ,spares, consumables ,reag for the quoted system as per condition bidding and to ensure compliance as the provisions of the Contract Acts as amended from time to time, a triparte reement is required to be concluded in prior to Final Acceptance of the stor stem .

(C) 30.Additional Terms and conditions & Scope of Work for CMC

Tenderer/Vendors/contractor should note that the following terms and conditic ill apply specifically in addition to the Rules and the Regulation as applicable t h provide services in the Government of India.

1. Comprehensive Annual Maintenance Contract must include Labour, spare Preventive Maintenance of all the excluding of battery, Accessories/Cons ables
2. The terms and conditions of the tender and the agreement executed wil binding on the vendor/contractor. This offer is being issued in accordance v the terms & conditions of NEIGRIHMS /Government of India and in the man specified herein shall operate to create a specific contract between the ver /contractor (with whom the contract referred to) on one part and NEIGRIHM hillong, on the other part.
3. The required spares to be replace must be genuine and certified from the .

4. Repairs to be undertaken should be within sp ified configuration and maintaining the integrati on internal circuit of equipment, any deviation o onfiguration/ specification the repair will not be

ceptable. After repairs, a certificate to the effect hat the equipment is in working order and safe f patient care and non-hazardous for the handler s all be submitted by the CMC holder.

5. Tenderer/Vendors/contractor is responsible to provide electrical and patie afety certificate after major repair of equipment which are used for direct p nt care.
6. The system must be checked & calibrated after every spare changes and ail service report must be submitted to the user & BME.
7. 2 nos of Periodic preventive maintenance is mandatory irrespective of ur ited service /breakdown calls.
8. Same /Similar Standby system must be provided by the bidder if the syst needs to send to workshop for any major repair.
9. Receipt of this offer may be acknowledged and a copy duly signed/stampe y the authorized signatory should be submitted before finalization of the ag ment.
10. The Performance security shall be denominated in any one of the forms na ly Account Payee Demand Draft or Fixed Deposit Receipt drawn from any n nalized bank in India or Bank Guarantee issued by a nationalized bank in In pledge in favor of Deputy Director, NEIGRIHMS, and Shillong-793018 for an ount equivalent to 3% of the total cost of annual CMC. The validity of the Fi Deposit receipt or Bank Guarantee will be upto 2 months beyond CMC perio

11. It may also be noted that there should be no egligence in providing services of any type, if an complaint is received the contract will be termin ed with immediate effect.

12. There will be 98% uptime warranty during CMC period on 24 (hrs) X 7 (da X 365 (days) basis, with penalty, to extend CMC period by double the dowr e period. The vendor shall ensure optimum uptime of the system during CM eriod, failing which the initiate shall initiate stern action, as deemed fit.
13. During Comprehensive Maintenance Contract period, the supplier shall vis t each consignee's site for preventive maintenance including testing and ca ation as per the manufacturer's service/ technical/ operational manual. The pplier shall visit each consignee site as recommended in the manufacturer' anual, but at least once in 6 months commencing from the date of the succ ful completion of warranty period for preventive maintenance of the goods.
14. Processing of bill may be considered on yearly basis with satisfactory repo rom the user department. The AMC/CMC bills should be certified by the cor ned Head of the Department/ In- Charge , BME and the respective DMS/MS.
15. Software updates should be provided free of cost during CMC. The first se e call by the team of service engineers should be within 7 days of issue of t order.
16. Settlement of disputes – Director, NEIGRIHMS or his authorized represent e shall be the final authority in all disputes and decision will be binding on a oncerned.
17. All other terms & conditions are as per award of contract mentioned in pre e.

18. Bidders are required to sign the CMC contract agreement within 15 (fifte) days from the issue of the letter of award/supply order, failing which EMD/ curity deposit may be forfeited or Contract declared null and void.

SOP for Operation of CSSD -RCC

_

_

CSSD OPERATIONAL TENDER FOR REGIONAL CANCER CENT

Range of STU	Nos. of Manpower	Remarks
O – 600	5	Manpower increasing according to the workl oad. One year experience i n the CSSD/Operation theatre
601 - 1200	6	
1201 - 2000	7	
2001 – 3000	9	
3001 Stu and above	10	

CONSUMABLE AND OTHER :

1. Electricity consumption bill.
2. Cleaning agent (High Level)
3. Disinfection agent (High Level)
4. Packing materials for Steam Sterilizing items
5. Biological testing for Steam Sterilizer
6. Process Chemical indicator tape for Steam Sterilizer
7. Documentation label for Steam Sterilizer
8. Labelling Gun for Steam Sterilizer
9. Integrating (Type 5) indicator Strips for Steam Sterilizer
10. De-Mineralized water

DESIG ODIFICATION :

1. Antimirobial PVC l cladding
2. Metal ceiling
3. Vinyl flooring

WORK FLOW :

1. Receiving and Supply (Door to door and dumbwaiters)
2. Disinfection of all surgical items

3. Surface cleaning and disinfection
4. Instrument, Linen and plasma sterile items packing
5. Dressing materials making
6. Cleaning of all surgical items
7. Record keeping

CONSUMABLE AND OTHER ITEMS PROVIDE FROM REGIONAL CANCER CEN E :

1. Compress Air
2. Tap water
3. Surgical Instruments
4. Linen and disposable drapes
5. S. S. Trays & Bowl
6. S. S. Dressing Drum
7. Instrument box
8. Gas plasma packing materials
9. Gas Plasma quality cheeked agent
10. All types of CSSD equipment
11. Dressing materials
12. Plasma Sterilant agent.

WORK FLOW :

Sterilization

STANDARD OPERATING PROTOCOL FOR CSSD

REGIONAL CANCER CENTER, HILLONG

SL. NO.	CONTENTS
1	CSSD PERSONNEL
2	DUTIES OF CSSD PERSONNEL AND REPORTING OFFICER
3	STANDARD OPERATING PROCEDURE OF CENTRAL STERILE SUPPLY DE PARTMENT
4	EQUIPMENT AND FURNITURE IN CSSD

5	CSSD QUALITY DOCUMENT
6	CSSD CONCEPT
7	CSSD DESIGN
8	OBJECTIVES
9	WORKFLOW
10	QUALITY ASSURANCE AND STERILZATION PROCESS MONITORING
11	DOCUMENTATION
12	RECORD KEEPING
13	CSSD INSTRUMENT TRAYS

CSSD PERSONNEL

1. CSSD OFFICER / MANAGER
2. CSSD SUPERVISOR
3. CSSD ASSISTANT GRADE – I
4. CSSD ASSISTANT GRADE – II
5. CSSD ATTENDANT / HELPER
6. CSSD CLEANER

DUTIES OF CSSD PERSONNEL & REPORTING OFFICER

CSSD OFFICER/MANAGER

- Ø Reports to Medical Superintendent.
- Ø Provides leadership and support to overall operations of the department.
- Ø Managing the activities of the department to achieve service delivery goals while effectively managing rces.
- Ø Overall responsibility for efficient running of the department.

- Ø To ensure strict adherence to laid down guidelines, standards and procedures.
- Ø Preparing plan and monthly operating report.
- Ø Developing and implementing quality standards in keeping up with current changes in practice.
- Ø Maintaining records and statistics and status of task reports.
- Ø Monitoring the departments' quality assurance, safety environmental and infection control programs.
- Ø Monitoring sterile service staff in achieving knowledge and competence.
- Ø Developing and implementing policies, procedures and maintaining quality assurance initiatives as rec by external review agencies to ensure that established HNC (Higher National Certificate) standards a ntained.
- Ø Skilled at development of policies, procedures and safe system of work.
- Ø Demonstrating professional development and ongoing education.
- Ø Proactive in health and safety identification and minimizing risks affecting CSSD practice.
- Ø Complies with policies, procedures and safe system of work.
- Ø Effective management of Budget monitoring related to CSSD activities.
- Ø High level of credibility within CSSD professionals, and other related disciplines.
- Ø To review and recommend the work procedures and practices in the department.
- Ø Has the authority to arrange for repair/conditioning of defective surgical instruments.

1

CSSD SUPERVISOR

- Ø Reports to the CSSD Officer / Manager.
- Ø Supervise all the CSSD work flow.
- Ø Primary duty centres on keeping the facility's stock of sterile devices up to date.
- Ø Maintenance of hygiene by ensuring the sterility of equipments in their charge.
- Ø Evaluation of equipment storage facilities and developing procedures to keep the equipment free of cc nation.
- Ø Assign duties to staff and monitor their performance.
- Ø Record keeping effectively tracking and monitoring the facility's use of sterile devices.
- Ø Help to identify and prevent other potential sources of infection in the facility.
- Ø Educate and guide new CSSD Technicians/Staffs and trainees in performing sterilization activities and c ing CSSD equipments.
- Ø Act as a liaison between their employer, the CSSD Officer/Manager and their staff.
- Ø Monitoring the department's quality assurance, safety environment and infection control programs.
- Ø Demonstration of departmental practices to MBBS and B.Sc. nursing students.
- Ø To sterilize items as per laid down protocol and ensure quality of sterilization.
- Ø Record maintenance for all CSSD related registers and documents.

- Ø Effective management of Budget monitoring related to CSSD activities.
- Ø Make the monthly and yearly statistics reports.
- Ø Reports all incidents and/or accidents.
- Ø Maintains inventory of Instruments and linen.

CSSD ASSISTANT GRADE I

- Ø Reports to the CSSD Supervisor.
- Ø Maintenance of all equipments in CSSD.
- Ø Operates sterilization machines effectively and ensures equipments are appropriately sterilized for use
- Ø Disassemble, sterilized, reassemble, pack instruments according to infection control guidelines.
- Ø Monitors the sterilization process of clinical equipments and healthcare supplies to ensure quality prod
- Ø Supervise at the time of washing, drying, and packing.
- Ø Records sterilizer test results, recognize faulty equipment and monitors expiry date and report to the S sor.
- Ø Proper handling, processing and storing sterilized items and timely distribution to the appropriate depa t.
- Ø Educate and guide new CSSD Technicians/ Staffs and trainees in performing sterilization activities and ting CSSD equipments.
- Ø Liaise with the biomedical section with regards to regular maintenance and calibration of machines in t t.
- Ø Daily report writing and keeping all records.
- Ø Record maintenance for sterilizer and other equipment.
- Ø Demonstration of departmental practices to MBBS and B.Sc. nursing students.

CSSD ASSISTANT GRADE II

- Ø Reports to the CSSD Supervisor.
- Ø Stationed in CSSD, but may be posted to different areas of the department i.e., decontamination, asse inspection, wrapping and sterilization.
- Ø Cleaning, washing and sterilizing of medical instruments and equipments.
- Ø Sort and assemble, protect/pack and label the instruments/equipments according to the checklist.
- Ø Maintain an accurate inventory of medical instruments/equipments.

- Ø Eye for details and enjoys routine work.
- Ø Comfortable with staggered shift duties.
- Ø Comfortable with handling loads/items.
- Ø To sterilize as per laid down protocols and ensures quality of sterilization.
- Ø Operates all types of sterilizer and other CSSD equipment.
- Ø Inventory of instrument tray from all wards, OPD's, Radiology and procedure room.
- Ø Record maintenance for sterilizer and other equipment.
- Ø Daily report writing and keeping all the records.

CSSD ATTENDANT

- Ø Reports to the CSSD Supervisor.
- Ø To help CSSD Assistant for proper functioning of CSSD.
- Ø Surgical Instrument washing, drying, packing etc and record keeping.
- Ø Receive dirty linen from various department and sends to the laundry unit for cleaning.
- Ø Receive clean linen from laundry and neatly arrange them on designated place.
- Ø Making dressing materials and other CSSD related work.
- Ø Surgical items receiving and dispatch.
- Ø Documentation and record keeping of received and dispatched items.

CSSD CLEANER

- Ø Reports to the CSSD Supervisor.
- Ø Mopping & cleaning of walls, racks, floor, dumb waiters, etc of CSSD.
- Ø Furniture and window panes are cleaned every morning.
- Ø Walls, lights and ceiling are cleaned weekly.
- Ø All trolleys are damp mopped every day.
- Ø The Sterilizer and all CSSD equipments are to be cleaned every morning with disinfectant solution.

3

–

–

–

STANDARD OPERATING PROCEDURE OF CENTRAL STERILE

PPLY DEPARTMENT

REGIONAL CANCER CENTRE, SHILLONG

CSSD Staff Entry

Changing Room Male/ Female

Receiving Dirty Items (Through receiving counter & door to door) **Su**
Sterile Items

(Through Clean Wi
Sorting (Surgical Instru
s) **& door to door)**

Surgical Instrument Treatment with high Level Disinfection Solution & Washe
nfector

Checking Instrument for any defect / malfunction

Instruments Assembling

Instruments Packing/Linen Packing

Moist Heat Sterilization **Gas Plasma Sterili**
n

Temperature: 121˚C and 134˚C **Temperature: 50˚C-55**

Quality Test: Chemical, Biological **Quality Test: Chemical and B**
ical

Bowie-Dick Test **Sterilize items: Rub**
ubing,

Sterilize items: Surgical Instrument, **Laparoscopic**
uments,

Linen, Dressing Materials, **Endoscopic Inst**
nts, Blades,

Containers, etc. **Cathe**
etc.

Sterile Store

4

–

EQUIPMENTS IN CSSD

SL.NO.	NAME OF EQUIPMENTS	QUANTITY
1	High pressure high vacuum steam sterilizer(12 STU, 8 STU and 6 STU) with loading trolley	3 Nos.
2	Plasma Sterilizer(120 – 130 litres)	1 No.
3	Drying heating cabinet (250-350 litres)	1 No.
4	Ultra Sonic Cleaner (40 litres)	1 No.
5	Washer Disinfectors (12 DIN)	2 Nos.
7	Gauge cutting machine	1 No.
8	Sealing Machine	1 No.
9	Incubator (Temp.:56˚C)	1 No.
10	RO cum De- Mineral Water Plant (500 litres/hr)	1 No.
11	Computer Set	1 No.
12	Sterile transportation trolley (1200mmX1200mmX650mm)	2 Nos.
13	Unsterile transportation trolley (1200mmX1200mmX650mm)	1 No.
14	Air Washer with filter	1 No.
15	Air Blower with filter	1 No.
16	Electrical Panel (300Kw)	1 No.

17	Washing Double Sink Basin	1 No.

–

–

–

–

–

FURNITURE IN CSSD

SL.NO	NAME OF FURNITURE	QUANTITY
1	Work Table	6 Nos.
2	Packing Table	3 Nos.
3	Free standing double basket rack	12 Nos.
4	Transfer trolley with 3 shelves	2 Nos.
5	Office working chair	6 Nos.
6	Visitor Chair	10 Nos.
7	Steel Almirah	3 Nos.
8	Book Shelves	2 Nos.
9	Staff locker 5 shelves	2 Nos.
10	Computer Table	1 No.

5

–

–

CSSD QUALITY DOCUMENTS GENERATED (REGISTER)

–

SL.NO.	QUALITY RECORD TITLE	QR.NO.
1	Stock Record	1
2	Daily Report Book	2
3	O.T. Receiving and Despatch Book	3
4	Biological Indicator Testing Record Book (Steam)	4
5	Steam Autoclave Record Book	5
6	Packing Record Book	6
7	Instrument Trays Inventory Book	7
8	Laundry Record Book	8
9	Plasma Autoclave Record Book	9
10	Linen Receiving and Used Record Book	10
11	Instrument Receiving and Used Record Book	11
12	Equipment Maintenance Record Book	12
13	Instrument Trays Content Record Book	13
14	Short Fall Record Book	14
15	Condemn Record Book	15
16	QR Title Record Book	16
17	Equipment Maintenance Record Book	17
18	De-Mineral Water Plan Maintenance Record Book	18
19	Biological Indicator Testing Record Book (Plasma)	19
20	Swab Testing Record Book	20
21	Daily Sterile Record Book	21
22	Instrument Receiving and despatch Record Book (Wards)	22
23	Instrument Receiving and Despatch Record book (OPD)	23
24		

	Bowie- Dick Test Record Book	24
25	Washer Disinfector Record Book	25
26	Heating Cabinet Record Book	26
27	Surgical Instrument Washing Record Book	27
28	Equipment Record Book	28
29	Recall Record Book	29

–

–

–

–

–

–

6

–

CSSD Quality Documents (File)

SL.NO	FILE NAME	FILE NO.
1	Letter Despatch	RCC/CSSD2023/01
2	Letter Received	RCC/CSSD2023/02
3	Circular Received	RCC/CSSD2023/03
4	Office Order	RCC/CSSD2023/04
5	Duty Roster	RCC/CSSD2023/05
6	Equipment	RCC/CSSD2023/06
7	Annual Report	RCC/CSSD2023/07
8	Monthly Statistics Report	RCC/CSSD2023/08
9	Annual Projection	RCC/CSSD2023/09
10	Leave	RCC/CSSD2023/10
11	Charge Report	RCC/CSSD2023/11

12	Purchase Order	RCC/CSSD2023/12
13	Complain In	RCC/CSSD2023/13
14	Service Report	RCC/CSSD2023/14

CSSD-CONCEPT

CSSD stands for Central Sterile Supply Department and forms the backbone of the Hospital with the responsib ility to reprocess surgical and other re-usable instrument. A CSSD should have facilities to receive, wash, dis nfect, pack, sterilize, sterile storage and distribute instruments to various respective departments and OTs.

The objective of establishing a Central Sterile Supply Department is to make reliably sterilized articles available at the required time and place for any agreed purpose in the hospital as economically as possible a nd in the shortest period of time.

CSSD plays a crucial role in Infection control in reducing the nosocomial infections in hospital. Nosocomial in ections are also known as hospital acquired infections. Hospital infection is the spread of pathogenic microorg anisms to patients as a result of the treatment or care given to them. These infections may be acquired by th e patient during his stay in the hospital or afterwards. Hospital patients tend to be particularly vulnerable to nfection, whether they are weakened by disease or injury or have the lowered resistance like infants and the elderly.

India has one of the highest rates of Nosocomial infections in the world. According to studies between 5-15 % of all the patients that are admitted to the hospital in India, develop infection from the hospital. A correctly de signed CSSD, equipped with highly reliable equipments goes a long way in reducing and minimizing the Noso omial infection in the hospital. In an ideal CSSD it becomes essential that correct protocols are defined and fo

lowed in order to implement the highest practices of sterilization.

CSSD DESIGN

A CSSD should be separated into three parts namely **the dirty zone, the clean zone and the sterile zone . All the three parts should be physically separate from one another and there should be an airlock between t he zones so that the contaminated air never enters the sterile zone. By strict separation of the soiled, disinfec ted and sterilized instrument, the idea is to permit only one flow of direction of materials from soiled to disinf cted to sterile and never the reverse. A well designed CSSD is essential not only for maintaining the sterility o materials and reducing the risk of infections, but also to ensure maximum efficiency of equipments and work low.

The instruments which are used in OT's and ICU's and various wards come directly to dirty zone of the CSSD t hrough lift for dirty instruments where they are arranged and loaded into the fully automatic washer disinfect ors. The Washer Disinfectors are double door type and they form the physical barrier between the dirty and c ean zone. The instruments are then washed, disinfected and dried in the Washer Disinfector and taken out fro m other side into the clean zone.

In the clean zone, the washed and disinfected instruments are arrange and inspected and then packed for ste rilization and then loaded into the sterilizers. The second barrier between the clean and the sterile zone cons sts of double door sterilizers. The sterilized instruments are taken out from the other side of the sterilizers int o the sterile zone where they are stored and dispatched to the OT's and ICU's and various wards.

–

–

–

OBJECTIVES:-

The main objectives of the CSSD are:

- Ø To provide the highest quality of clean, disinfected and sterilized instruments.
- Ø To provide supplies of instruments, linen packs, basins and other sterile items used in patient care.
- Ø To act as a central department with the infrastructure and trained manpower to take care of the sterilizat on need of various departments and OTs in a Hospital.
- Ø To ensure that the latest standards and trends in sterilization are followed and updated.
- Ø To reduce the Nosocomial infection in a hospital.
- Ø To be able to supply the sterilized instruments back quickly and efficiently with the highest reliability to e nsure smooth flow of instruments.
- Ø To maintain records of flow of instruments and technical data of sterilization and disinfection for every cy cle and every instrument.
- Ø To maintain an inventory of supplies and equipments.

WORK FLOW :-

FUNCTIONS

- · Transportation and Receiving
- · Cleaning
- · Inspection
- · Assembling
- · Packaging
- · Sterilization
- · Sterile Storage
- · Transportation and Sterile Supply

1. TRANSPORTATION AND RECEIVING:

After use, for example in the operating theatre or other treatment room, the soiled materials are collected an sported in suitable containers and trolleys to the CSSD. Transportation is an important part of the sterilization

ss and should be done in closed trolleys or containers to minimize the risk of infection from contaminated ins
nts. Ideally, separate routes for transportation of dirty and sterile materials should be provided and the lifts u
ould also be separate to minimize the risk of cross contamination.

2. CLEANING:

The instruments which are used in OTs and ICUs and various ward come directly to the dirty zone of the CSSD
ugh the lift or receiving counter for dirty instruments where they are arranged and loaded into the fully auton
Washer Disinfectors. The Washer Disinfectors are double door systems and they form the physical barrier bet
the dirty and clean zone. The used instrument are then washed, disinfected and dried in the Washer Disinfect
nd then taken out from the other side into the clean zone.

2.1 Requirements of Washing Area:

- Facilities of clean cold and warm water.
- If the water is hard it needs to be softened or preferably de-mineralized to protect the instruments f
  ard ion deposits.
- Stainless steel sinks, sufficiently deep, at least 12 inches or more.
- Water, air pressure guns and water spay or shower.
- Perforated or preferably wire mesh trays.
- Cleaning Agents- Chemical/Enzymatic
- Disinfecting Agents
- Soft bristle brushes
- Ultrasonic cleaner
- Washer Disinfector

2.2 Receiving of Used Items

- The personnel involved in cleaning must be properly attired in PPEs such as protective gown or plast
  on, cap, mask and should wear gloves.
- At CSSD, the instruments must be checked for proper count and examined for any obvious damage a
  rted for manual or machine cleaning.

2.3 Cleaning Procedure

- Manufactures recommendations for operation of cleaning equipment as well as supplies like deterge
  ts and disinfectants etc., should be strictly followed
- Before cleaning is carried out, instruments that are made of more than one part must be disassemb
  d. The parts must be tied together to avoid confusion while packing the instruments.
- Segregate the instruments, depending on the condition of surfaces to be cleaned (glass, steel, rubbe
  plastic etc.,)
- Pass water under pressure through cannulated items such as catheters.
- Take special care of areas which are not readily exposed such as grooves in atraugrip forceps, teeth
  n dissecting forceps, box locks of instruments, ratchets of handles other instruments which are made
  p of more than part.
- If certain devices cannot be submerged under water they may be wiped with a detergent wetted clo
  , followed by a clean cloth.
- If there is any dried blood on the instruments, hydrogen peroxide can be used as a solvent. Do not le
  ve the instruments in it as it could be corrosive.

2.4 Manual Cleaning

- Manual cleaning is done when machine cleaning is not possible, usually for delicate instruments and tensils.

- Manual cleaning involves placing the items to be cleaned in a sink or basin containing water and cle ning solution.
- Each item must be scrubbed with a soft bristled brush.
- Drill bits and blades should be soaked and cleaned with toothbrush.
- Avoid using hard brushes or abrasive powder to clean, as the same will damage the instruments.
- Motorized hand pieces should be cleaned with sprays recommended by manufacturers, with the hel of gauze pieces.

2.5 Principles of Ultrasonic Cleaning

- Ultra means ‘beyond’ and sonic means ‘sound’ hence these cleaners make use of vibrations with fre uency greater than those of sound.

- When an ultrasonic wave passes through a liquid it makes the liquid vibrate very fast. Due to this sm ll gas bubbles develop, become larger and implode.
- This draws out tiny particles of dirt from crevices such as the hinges and serrations on instruments r ulting in thorough cleaning, especially hard to reach areas where manual scrubbing would not be pos ble.
- It has a brushing effect, more efficient than manual cleaning.

2.6 Ultrasonic Cleaning Method

- To prevent spillage, noise and aerosol formation, the unit should have a lid.
- Recommended concentration of cleaning agent and a temperature between 35 and 50˚ C should be sed.
- Use wire mesh trays and do not overload. The instruments tray is to be kept in a detergent bath for – 10 minutes or as recommended by the manufacturer.
- Use warm water above 40˚ C to stimulate de-gassing in the bath, but not more than 60˚C to avoid p tein coagulation.
- Change the cleaning solution whenever it is dirty, at the start of every shift or as recommended by anufacturer.

2.7 Washer – Disinfector Cleaning Method

- This equipment is programmable with respect to concentration of cleaning agent, number of rinse cy les, any other treatment post washing like use of lubricants/neutralizer, thus depending on the items o be cleaned, appropriate program needs to be selected.

- Cleaning indicator should be used to verify the cleaning.
- Here, disinfection is achieved by hot water up to 70˚ C.
- Temperature of water for pre-rinse, wash, post-rinse and disinfection is controlled in the machine.
- Detailed operating protocol should be obtained from manufacturers.

2.8. Cleaning Agents

- Water alone is not directly suitable for removing hydrophobic substances such as oils, fats and prote s etc. Cleaning agents like detergents or enzymatic cleaners should be used.
- Earlier soaps were used made from animal fats combined with alkalis like sodium or potassium hyd xide. These are very harsh and never used for cleaning instruments.
- Detergents lower surface tension and dislodge, disperse and hence remove soils from surface being eaned by suspending them in a liquid medium.
- Detergents should be compatible with the equipment with which they are used e.g., foaming deterg nts may not be suitable for mechanical washing.
- They should also be compatible with the material being cleaned and the quality of water (soft or har .
- Enzymatic Cleaners are biological catalyst molecules which help break down or digest large organic olecules like proteins, fats and starch into smaller ones.

2.9 Rinsing

- After cleaning, residual loosened dirt and cleaning agent residues may be left on the instruments an if not rinsed properly, the will hamper sterilization or left over chemicals will cause corrosion.

- The instruments must then be washed by spraying or washing under running water.
- Preferably last rinse is done with de-mineralized or de-ionized water to prevent stains, rust or corros n.
- If possible, wash instruments in their racks/holders to protect from damage as long as all parts are e posed.

2.10 Inspection

- It is essential to verify that the cleaning process has been effective in removing all visible soil from e ery surface (external and internal) of the instrument / devices, by visual inspection.

- When items are clean and free from dirt, soil and oil, water will run off in sheets. If the item is dirty, oplets or beads will form on the object.
- To carry out the visual inspection, it is mandatory to have sufficient illumination in the work place an if possible a magnifying lens/device.
- Reusable instruments / devices should be purchased only when assurance has been provided by th manufacturer that they can be safely and effectively cleaned and further reprocessed.
- If this is not possible, the problems and associated patient risk should be brought to the notice of the nfection Control Committee/ Microbiologist.

2.11 Instrument Lubrication

- Water soluble lubricants (instrument milk) could be used after the cleaning process.

- Lubricants which inhibit the passage of steam e.g., oil, paraffin should not be used. Steam penetrabl lubricants and sprays should be used.

2.12 Drying

- After washing, instruments need to be dried as water droplets would interfere with most of the steril ation processes. E.g., in case of steam sterilization, excess water would not be re-vaporized after the ocess, causing wet packs.

- In case of gas plasma, the cycle is aborted if any moisture is present in the load.
- In case of chemical sterilization/disinfection residual water may dilute the agent. In this case remov as much water as you can, since complete drying may not be possible.
  Drying is achieved by
- Items can be wiped with a clean, non fiber shedding cloth manually, usually followed for bigger items ike basins, mayo trays etc.

- Moisture, dust and oil free compressed air can be forced over the instruments and through lumens t remove water droplets.
- Items can be dried in a drying cabinet with a thermostat and air circulation facility to maintain a fixe uniform temperature. This is the best method as it does not involve manual handling of the device aft cleaning, as well as saves labour.

3. INSPECTION:

- Every item must be inspected to verify cleanliness and also tested to verify functionality.

- The instrument must perform effectively every time it is used e.g. cutting edge and sharp, tips are a gned, and all moving parts operate smoothly.
- When the instrument/ device are disassembled for cleaning it should be reassembled to perform the unctionality test.
- The manufacturer of each instrument/ device should provide the specifications, methodologies and ols needed to perform functionality testing.

3.1 Instrument Marking

This is required to allow identification by department, specialty, set, surgeon etc.

Common methods are:

- **Instrument marking tape:** This has an adhesive that adheres to stainless steel. It is applied by h pital personnel after cleaning the surface of the instrument. It should be placed on the area that woul not impede the action of the instrument of the surgeon. It is available in a variety of colours.
- **Acid based and Laser etching:** It can be done by the instrument manufacturer or the hospital. Er raving should never be used.
- **Color coding and banding:** This is done by the instrument manufacturer. E.g. Ethicon Ligaclip App cators. It eventually chips and loosens and requires refurbishing.

4. ASSEMBLING:

- Instruments which are not working should be removed and replaced. The removed instrument shoul be sent for repairs or condemned.

- A checklist with a signature of the person responsible for packing should be added at least in large s s. It should be signed by the person using the set and later by person receiving the used set.
- The contents of the pack should be changed only through amendment duly authorized by the CSSD -Charge based upon either verbal or written requests from the concerned users.
- The contents of the pack should be as per the user's requirement. For the same procedure/ surgery e set should be uniform.
- If due to a surgeon's preference or an unusual situation an additional device is required, this should e packed separately and mentioned in the checklist of the pack.

5. PACKAGING:

In the clean zone, the washed and disinfected instruments are arranged and inspected and then packed for erilization and then loaded into the sterilizers. The second barrier between the clean and the sterile zone cor sts of double door sterilizers. The sterilized instruments are taken out from the other side of the sterilizers in the sterile zone where they are stored and dispatched to the OTs and ICUs and various ward.

5.1 Types of Packaging Materials:

1. Linen/SMMS wrappers.

2. Paper
3. Paper Plastic
4. Sterile container.

5.1.1 Linen/ SMMS Wrappers

- Wrappers are used to provide protection against contamination as well as to serve as effective dust over.

- They must be enough to cover the item.
- Linen wrappers are generally re-usable.
- To enhance barrier qualities, a double layer wrapper is recommended.
- Reusable fabrics should be laundered before used.
- SMMS wrapper should be 53 GSM blue in color.

5.1.2 Paper

- They accommodate small medical devices and porous or soft items (like dressing material).
- Medical grade variety (made up from virgin pulp- not recycle and without toxic adhesives in case of nvelopes.)
- Minimum grade recommended is 60 GSM.

5.1.3 Paper Plastic

- Paper Plastic used for Gas Plasma and Steam they consist of one layer paper or plastic and one laye of plastic composite transparent film which is heat sealed along the lengthwise edges or tubes dispe ed in rolls and reels.

5.1.4 Sterile Container

- They come in various sizes and designs of box like structures with sealable, removable lids with perf ations
- They are constructed of anodized aluminum, stainless steel, high temperature plastics or combinatic s of these.
- The perforations in the top and bottom surfaces are covered internally by sterilant permeable micro al filters.
- These filters are made of single used material held in place by retention plates or reusable valves w ch allow sterilants to enter during sterilization phase and close drying phase.
- Unless specified by manufacturers these should not be used in gravity displacement steam sterilizer
- These must have an inner tray to facilitate aseptic handling.
- In some cases, the time of sterilization and drying phase needs to be extended when these are used

6. STERLIZATION

After packaging the load is ready to be sterilized. In the sterilizer micro-organisms remaining after the cleani ocess are destroyed. Their number are reduced to probability, which is considered safe : the Sterility Assura evel. A range of methods are in use, all with their specific field of application : **Moist heat(Steam), Liquid acetic Acid Sterilization and Gas plasma sterilization.** The most common and safe method used in hea cilities is the sterilization by moist heat(Steam) using pressurized high-temperature steam. The machine use sterilization with steam are know as steam sterilization. Sterilizers should meet the stringent technical stand o performance and safety. To ensure the safety to the staff and patient, for each sterilizer used for meadical ies, all processes in combination with each type of load in its packaging should be validated.

6.1 Moist heat (Steam) Sterilization

The two most common temperatures used are 121˚C and 134˚C. All types of wrapped Metal surgical instrume nt, linen, Dressing material, S. S. tray, Rubber items etc. are sterilized by moist heat (steam).

Common 121˚C and 134˚C gravity displacement steam cycles

Load Contents	Sterilization time(min) Tem perature121 ˚C Pressure 1.2kg/cm²	Sterilization time(min) Temperature134 ˚C Pressure 2.2kg/cm²
Metal surgical instrument	20	5-7

Linen	30	5-7
Dressing material	30	5-7
S. S. tray	20	5-7
Container	20	5-7
Rubber	20	-

–

–

–

6.2 Liquid Per acetic Acid sterilization

- Per acetic acid is a most commonly used liquid sterilant.
- It is powerful microbicidal at concentration less than 1%.
- It maintains its efficacy in the presence of organic soils.

6.3 <u>Hydrogen peroxide gas Plasma Sterilizer</u>

–

Many articles which need to be reprocessed by the CSSD are sensitive to heat or moisture and hence ot be sterilized by steam or any other high temperature method.

- Common 50°C – 55°C H_2O_2 gas Plasma cycle
- Gas Plasma is a highly ionized or highly charged fourth state of matter, created by deep vacuum anc electromagnetic energy.
- Plasma is a state of matter in which negatively charged particles or electrons exist in an unstable a d excited state.
- Generally hydrogen peroxide in the gaseous phase is used to create this plasma.
- Microbicidal activity is due to highly reactive species like electrons and ions.
- 95% of medical devices are compatible with H_2O_2 gas Plasma sterilizer.
- It has a short cycle time of 60-75 minutes.
- No toxic chemical residues, by-products of sterilization being oxygen and water.
- All types of plastics materials, all types of rubber tubings, laparoscopic instruments, blades, knives, calpels, scissors, endoscopic instruments, sharp instruments etc.

3. STERILE STORAGE

- After the cycle is over, only items that are visibly dry should be removed and are stored in a dedicat d, ultra clean storage area.
- Sterile goods should be stored in the order of their date of expiry. This helps in reducing items to be e- sterilized. First Expiry First Out or FEFO method should be followed.
- Conditions and procedures should be implemented to avoid compromising the integrity of the packa e.
- The most important thing to remember is that sterile packages should be kept away from moisture, uid, dirt, dust and debris.

- Outside the CSSD storage of sterile supplies is often neglected, hence it should be supervised by CSD personnel.
- Personnel responsible for handling these should be adequately trained in aseptic procedures.

4. STERILE SUPPLY

- Sterile items for Operation Theatres are supply through Dumbwaiters.
- Transportation to and from sterile area should be carried out in covered or enclosed cart.
- The carts should have a solid bottom to prevent dirt entering as the wheels move.
- The top and bottom of the carts including wheels must be washed periodically.
- The trolleys should be in good condition as damaged carts can allow the entry of air due to turbulence during movement.
- Avoid contact with the sterile packs as far as possible. (i.e. minimum handling)
- Sterile packs should not be hugged, squeezed, bumped into, leaned on, or touched while counting.
- Any sterile items that fall on the floor or wet should be consider contaminated and sent for reprocessing.
- Packages should not be dragged or pushed against any surface as this could cause the wrappers to become loose or create a tear or hole.
- Do not use paper clips or rubber bands to hold packages together which can create holes/ constrict and crease or slice through the pack.

QUALITY ASSURANCE AND STERILIZATION PROCESS MONITORING

1. Chemical Indicators

- These are substances which melt at high temperatures and are put in sealed ampoules or strips impregnated with certain dyes which change color when the required temperature are reached.
- Chemical indicator reaches their end points in the form of chemical (color) or physical (solid to liquid change.
- They monitor one or more parameters of the sterilization process.
- They show that the item has been through the sterilization process, not that the item is sterile.

Class 1

- They are external process indicators.
- External process indicators inform the user that the pack has been through the sterilization process and are often used as sealers for packages.
- The Documentation Labeling Gun is used to print date, time, cycle batch number and expiry date on every pack.

Class 2

- It is used in the Bowie and Dick test for pre–vacuum steam sterilizers.
- It is used in other specific test procedures like process challenge device.

Bowie and Dick test

- It is used only for pre-vacuum steam sterilizers to monitor vacuum level, detect air leaks and steam quality.
- This test needs to be performed for 3.5 - 4minutes at 134˚C and 10 – 15 minutes at 121˚C.
- Should be done in the first cycle each day, after warm up.
- A satisfactory result is indicated by uniform color change on test sheet.

Class 5

- They are internal pack integrating indicator.
- They also function as integrators.
- They respond to all parameters of sterilization over specified temperatures.
- Their performance is compared to the inactivation of test organism.
- They can be used in both steam and Gas plasma cycles.

2. Biological Indicators (BIs)

- Standardized and certified biological indicators are used to monitor sterilization process.
- They ensure proper packing, loading, sterilant quality and functioning of equipment.
- They contain a certain number of spores (about 1 million) of micro-organism most resistant to the st rilization process.

Types of BIs

- The spore strip or disc is packed in vial with sealed ampoule of growth medium. These are activatec by crushing the ampoule, allowing micro-organisms to come in contact with the growth media. When ncubated the spores grow and cause color change in medium within 24-48 hours.
- In another method BIs employ a florescent light to determine an enzymatic reaction that indicates c ll division is occurring. This type is “rapid readout” and results can be obtained as quickly as possible.
- Steam sterilizer use Geobacillus stearothermophillus as the test organisms.
- Hydrogen peroxide use Geobacillus stearothermophillus or Bacillus Atropheus.

Method of testing

- Two indicators are to be used per test, the experimental indicator and the control indicator.
- The experimental indicator is placed into the sterilizer at the place most difficult to reach. (E.g. Abov drains in steam sterilizer and diagonally opposite to cartridge/inlet in Gas Plasma sterilizer.
- The control indicator is not put in the sterilizer, but incubated along with the one that underwent ste lization.
- The control indicator is expected to grow but not the experimental one.

Frequency of testing

- For steam sterilizer and Gas Plasma sterilizer, the BI should be used daily.

Shelf life

- It depends on the quality of the wrapper.
- It also depends on storage conditions

- Conditions during transport
  - Through dedicated lifts
  - Clean corridors
- Amount of handling
  - Minimum handling
  - Avoid squeezing etc.

Expiry Date

Arrangement of sterile packs should be in sequence of their expiry date:
Normal self life is given as follows:

- Ø Linen and SMMS packed trays or set 7 days
- Ø Medical grade paper packing 1 month
- Ø PVC peel pouch packing 1 year

Event related expiry: Items or packs that hasn't reached their expiry dates should be considered u sterile if wrappers are found to be soiled, torn, wet or kept in areas that are not designated for sterile torage.

Housekeeping practices (Maintenance)

- Flooring should be cleaned twice a day with High Level Surface Disinfector.
- Sterilizer panels, unloading trolleys, pass boxes/ hatches dumb waiters, furniture's, walls, gl ss panes etc. should cleaned with High Level Surface Disinfector.
- A check list should be prepared to facilitate total coverage.

DOCUMENTATION

-

- Assures the monitoring of the sterilization process i.e., assures that the cycle parameters ha n met, and establishes accountability.
- By knowing the contents of each load that was processed and the lot number, sterile process ersonnel can determine how critical the recall is, should the sterility of the load becomes susp .
- From a legal point of view, if your facility was to be sued for malpractice concerning a nosoc nfection, sterilization record can shift the burden of proof to the plaintiff.
- Remember not documented is consider as not done.
- If departments are wise, issue records are maintained, it helps in **Recall** in case of sterilizat ure.

RECORD KEEPING

- Lot control numbers should be affixed on the product.
- At the beginning of the cycle, the date, time, sterilizer, operator and cycle identification shou marked on the chart.
- At the end of the cycle, the response of CI should be recorded.
- Results of BI should be recorded when obtained.
- The sterilization record should be examined and attested.
- Load record log should be maintained.

CSSD INSTRUMENT TRAYS

1	Dressing Tray

2	Catheter Tray
3	Suture Tray
4	Suture Removal Tray
5	Perineal Care Tray
6	Bone Marrow Tray
7	Cut Down Tray
8	Chest Tube Tray
9	Tracheotomy Tray

TITLE: - DRESSING TRAY

SL. NO.	INSTRUMENT NAME	INSTRUMENT SIZE	QUANTITY	REMARKS
1	S. Steel Tray	220 mm x 150 mm	1	
2	Artery Forceps	150 mm	1	
3	S. S. Bowl	80 mm	1	
4	Dissecting Forceps	150 mm	1	
5	Dressing Material	-	.....	
6	Wrapper	1000 mm x 1000 mm	1	

TITLE: CATHETERIZATION TRAY

SL. NO.	INSTRUMENT NAME	INSTRUMENT SIZE	QUANTITY	REMARKS
1	S. Steel Tray	250 mm x 200 mm	1	
2	Artery Forceps straight	150 mm	1	
3	Sponge Holding Forceps	175 mm	1	
4	S. S. Bowl	80 mm	1	
5	Eye Towel	450 mm x 450 mm	1	

6	Skin Towel	450 mm x 450 mm	2	
7	Dressing Material	-	.....	
8	Wrapper	1000 mm x 1000 mm	1	

TITLE: - SUTURE REMOVAL TRAY

SL. NO.	INSTRUMENT NAME	INSTRUMENT SIZE	QUANTITY	REMARKS
1	S. Steel Tray (Kidney Tray)	250 mm	1	
2	Suture Cutting Scissor	150 mm	1	
3	Mosquito Forceps Straight/Curve	100 mm	1	
4	Dissecting Forceps	150 mm	1	
5	S. S. Bowl	80 mm	1	
6	Dressing Material	-	.....	
7	Wrapper	750mm x 750 mm	1	

20

TITLE: - PERINEAL CARE TRAY

SL. NO.	INSTRUMENT NAME	INSTRUMENT SIZE	QUANTITY	REMARKS
1	S. Steel Tray	250 mm x 150 mm	1	
2	Sponge Holding Forceps	175 mm	1	
3	S. S. Bowl	80 mm	1	
4	Dressing Material	-	.....	
5	Wrapper	1000 mm x 1000 mm	1	

TITLE: - CHEST TUBE TRAY

SL. NO.	INSTRUMENT NAME	INSTRUMENT SIZE	QUANTITY	REMARKS
1	S. Steel Tray	250 mm x 200 mm	1	

2	Artery Forceps straight	150 mm	1	
3	Artery Forceps Curved	150 mm	1	
4	Sponge Holding Forceps	175 mm	1	
5	Needle Holder	150 mm	1	
6	Toothed Dissecting Forceps	150 mm	1	
7	S. S. Bowl	80 mm	1	
8	Eye Towel	450 mm x 450 mm	1	
9	Skin Towel	450 mm x 450 mm	2	
10	Small Mackintosh	450 mm x 450 mm	1	
11	Dressing Material	-	.....	
12	Wrapper	1000 mm x 1000 mm	1	

TITLE: - BONE MARROW TRAY

SL. NO.	INSTRUMENT NAME	INSTRUMENT SIZE	QUANTITY	REMARKS
1	S. Steel Tray	225 mm x 150 mm	1	
2	Artery Forceps straight	150 mm	1	
3	S. S. Bowl	80 mm	1	
4	B. M. Needle	No.18	1	
5	B. M. Needle	No.16	1	
6	Eye Towel	450 mm x 450 mm	1	
7	Skin Towel	450 mm x 450 mm	2	
7	Dressing Material	-	.....	
8	Wrapper	900 mm x 900 mm	1	

TITLE: - SUTURE TRAY

SL. NO.	INSTRUMENT NAME	INSTRUMENT SIZE	QUANTITY	REMARKS

1	S. Steel Tray	225 mm x 150 mm	1	
2	Artery Forceps straight/Curve	150 mm	1+1	
3	Allis Tissue	150 mm	1	
4	Needle Holder	150 mm	1	
5	B. P. Knife Handle	No. 3	1	
6	Mayo Scissor	150 mm	1	
7	Dissecting Forceps Toothed	150 mm	1	
8	Small Bowl	80 mm	1	
9	Eye Towel	450 mm x 450 mm	1	
10	Skin Towel	450 mm x 450 mm	2	
11	Dressing Material	-	.....	
12	Wrapper	1000 mm x 1000 mm	1	

21

TITLE: - CUT DOWN TRAY

SL. NO.	INSTRUMENT NAME	INSTRUMENT SIZE	QUANTITY	REMARKS
1	S. Steel Tray	250 mm x 200 mm	1	
2	Artery Forceps straight/Curve	150 mm	1+1	
3	Aneurysm Needle	-	1	
4	Mosquito Forceps Straight	100 mm	1	
5	Mosquito Forceps Curve	100 mm	1	
6	Mayo Scissor	150 mm	1	
7	Iris Scissor	-	1	
8	Dissecting Forceps	150 mm	2	
9	Single Hook Retractor	-	1	

10	Needle Holder	150 mm	1	
11	B. P. Knife Handle	No. 3	1	
12	Allis Tissue Forceps	150 mm	1	
13	Sponge Holding Forceps	175 mm	1	
14	Small Bowl	80 mm	1	
15	Eye Towel	450mm x 450mm	1	
16	Skin Towel	450mm x 450mm	2	
17	Wrapper	1000mm x 1000mm	1	

TITLE: - TRACHEOSTOMY TRAY

SL. NO.	INSTRUMENT NAME	INSTRUMENT SIZE	QUANTITY	REMARKS
1	S. Steel Tray	1200mm x 1000mm	1	
2	Artery Forceps straight/Curve	150 mm	1+1	
3	Aneurysm Needle	-	1	
4	Mosquito Forceps St.	100 mm	2	
5	Mosquito Forceps Curve	100 mm	2	
6	Mayo Scissor	150 mm	1	
7	Tracheal Dilator	-	1	
8	Single Hook Retractor	-	2	
9	Dissecting Forceps	150 mm	2	
10	Double Hook Retractor	-	2	
11	Needle Holder	150 mm	1	
12	B. P. Knife Handle	No. 3	1	
13	Allis Tissue Forceps	150 mm	1	
14	Sponge Holding Forceps	175 mm	1	

15	Sinus Forceps	-	1	
16	Towel Clip	-	4	
17	Kidney Tray Small	150 mm	1	
18	Small Bowl	80 mm	1	
19	Eye Towel	450mm x 450mm	1	
20	Skin Towel	450mm x 450mm	3	
21	Wrapper	1200mm x 1200mm	1	

Amendment in technical specification for Specifications for SITC and Operation of CSSD at RCC must included in the compliance report failing which bid will not be consider for Evaluation process		
GeM E–Tender (Bid) Document Number : GEM/2024/B/4792508,16-03-2024		
Reference to representations received from various bidders following amendments in technical specification was considered for wider participation		
Sl no	**Tendered Technical Specification**	**Amended as**
	Technical Specification for Steam Sterilizer (12 Stu) - 1 Nos	**Technical Specification for Steam Sterilizer (12 Stu)**
1	The Sterilizer should have the autoclaving chamber capacity of 900- 1000 liters ± 3 %	The Sterilizer should have the autoclaving chamber capacity of 12stu/ 1000 liters + 3 %
5	The Sterilizer should be equipped with 134 degree Celsius pre-vacuum, 121 degree Celsius Liquid cycle, 134 degree Celsius Gravity Cycle and only for 121 degree Celsius regular cycle with 45 minutes exposure time. All these cycles s	The Sterilizer should be equipped with 134 degree Celsius pre-vacuum and 121 degree Celsius regular cycle with 15 - 18 minutes exp

	hould be pre feed into the software pro grammed control system and should b e validated as per AAMI ST 8/EN 285 /U S FDA/ BIS Pressure standards /CDSCO standards.	osure time. exposure t ime. All these cycles s hould be pre feed into the software program med control system an d should be validated as per AAMI /ANSI/Eur opean CE /US FDA/ BIS Pressure standards /C DSCO standards/ ISO 1 7665-1 or latest
24	The jacket should be made of 316 L qu ality stainless steel with pressure gauge.	The jacket should be made of 316 L quality stainless steel with/wit hout pressure gauge.
26	Steam generator should be made of 316 grade stainless steel material. The steam generator should have chlorid e free mineral wool or mineral glas s wool thickness of 25 mm to 50 mm in sulation sheet.	The sterilizer chamber is completely insulate d with a 30–80 mm chl oride free mineral woo l, encased in rigid she et aluminium housing
39	The Sterilizer should have touch sensiti ve 7 inch LCD color display control syst em with battery back-up and digital th ermal printer for online record.	The Sterilizer should h ave touch sensitive 7 inch or more LCD colo r display control syste m with battery back-u p in both the side of s teriliser and digital the rmal printer for online record.
51	The range of safety features alarm sho uld be audio and visual include over te mperature, pressure sensor failure, phase time-out, pressure relief safet y valve, doors not properly closed, p ower failure if more than 25 second s, Continuous self-checking of all the s afety devices, low water level, water in chamber etc. should be possible after t he completion of each cycle.	The range of safety fe atures alarm should b e audio and visual incl ude over temperature, pressure sensor failure , phase time-out, press ure relief safety valve, doors not properly clo sed, power failure if m ore than 10 seconds, Continuous self-checki ng of all the safety dev ices, low water level, water in chamber etc. should be possible aft er the completion of e ach cycle.
61	1. The sterilizer should confirm th e Europe EN 285:2006 standard / A	1. The sterilizer sho uld confirm to the stan

	AME ST 8 standard or BIS equivalent st andards for Hospital Sterilizers.	dards for Hospital Ster ilizers ISO 17665-1 or l atest .
61	4. The sterilizer should confirm th e Medical Device Directive MDD 93/ 42/EEC amended by Directive 2007/47/ EC.	4. The sterilizer sho uld confirm the Medica l Device Directive MD D 93/42/EEC amended by Directive 2007/47/EC / MDR Co mpliant.
	7. The manufacturing company shou ld be bear the ISO 9001:2008.	7. The manufacturing company should be be ar the ISO 13485:2016+A11:2021 or latest
	8. The manufacturing company sho uld be bear the Quality Management S ystem, ISO13683:2003 or ISO 13485:20 03 for Medical Devices	Deleted
	9. The manufacturing company shou ld be bear the EN ISO 14001:2004.	Deleted
62	The manufacturing firm should have dir ect operations in India with own trained service set up, engineers to ensure ser vice backup, in time quality services, in stant availability of spares or the deale r should have own trained service engi neers / technicians to ensure service b ackup, in time quality services, instant availability of spares	The manufacturing or i ts Authorised distribut or should have direct operations in India wit h own trained service set up, engineers to e nsure service backup, in time quality service s, instant availability o f spares or the dealer should have own train ed service engineers / technicians to ensure service backup, in tim e quality services, inst ant availability of spar es. In case of authoris ed distributor, Manufa ctures undertaking mu st be attached with re gard to compliance of all terms and conditi ons of the tender inclu ding service provision through out the warra nty and CMC period , i n case of change in au thorised distributors /a

		uthorised distributor f ailed to provide servic es as per the terms an d conditions .
65	The Sterilizer should have electronic water saving control or eco water re circulation system for external coolin g condenser for condensing the exha ust chamber steam to acceptable te mperature to reuse in the internal s ystem & ensure the quoted system should be a least water consumptio n model & specify the water consumpti on	The Sterilizer should have electronic water saving control or eco water recirculation sy stem for external co oling condenser for c ondensing the exhaus t chamber steam to ac ceptable temperature to reuse in the internal system & ensure the q uoted system should be a least water consu mption model & spec ify the water consum ption ,Bidder need t o do necessary arrang ement for the same.
70. 2	5.The equipment complies with the requirement of the Medical Device D irective of class I equipment and Electromagnetic compatibility; all s upporting documents must be provided .	5.The equipment co mplies with the requ irement of the Medic al Device Directive of class I equipment , MDR compliant and Electromagnetic comp atibility; all supporting documents must be pr ovided.
	2.Standards, Safety and Training	
	1.Should be Europe EN 285:2006 stand ard / AAME ST 8 standard or BIS equiva lent standards	1.Should be AAMI /ANS I/European CE /US FDA / BIS Pressure standar ds /CDSCO standards/ ISO 17665-1 or latest
	Electrical safety conforms to standards for electrical safety IEC 60601- 1 (Or eq uivalent International / National standa rd) general requirement for Electrical safety of Medical equipme nt.	Electrical safety confor ms to standards for el ectrical safety IEC 606 01- 1 or latest (Or equi valent International / National standard) general requirement f or Electrical safety of Medical equipment.
Technical Specification for Steam Sterili		**Technical Specificat**

zer (8 Stu) - 2 Nos		**ion for Steam Sterili zer (8 Stu)**
1	The Sterilizer should have the autoc laving chamber capacity of550-600 li ters + 3 %	The Sterilizer should h ave the autoclaving ch amber capacity of 8 st u / 600 liters + 3 %
5	The Sterilizer should be equipped with 134 degree Celsius pre-vacuum, 121 d egree Celsius Liquid cycle, 134 degree Celsius Gravity Cycle and only for 121 degree Celsius regular cycle with 45 mi nutes exposure time. All these cycles s hould be pre feed into the software pro grammed control system and should b e validated as per AAMI ST 8/EN 285 /U S FDA/ BIS Pressure standards /CDSCO standards.	The Sterilizer should b e equipped with 134 d egree Celsius pre-vacu um and 121 degree C elsius regular cycle wit h 15 - 18 minutes exp osure time. exposure t ime. All these cycles s hould be pre feed into the software program med control system an d should be validated as per AAMI /ANSI/Eur opean CE /US FDA/ BIS Pressure standards /C DSCO standards/ ISO 1 7665-1 or latest
24	The jacket should be made of 316 L qu ality stainless steel with pressure gauge.	The jacket should be made of 316 L quality stainless steel with/wit hout pressure gauge.
26	Steam generator should be made of 316 grade stainless steel material. The steam generator should have chlorid e free mineral wool or mineral glas s wool thickness of 25 mm to 50 mm in sulation sheet.	The sterilizer chamber is completely insulate d with a 30–80 mm chl oride free mineral woo l, encased in rigid she et aluminium housing
39	The Sterilizer should have touch sensiti ve 7 inch LCD colour display control sys tem with battery back-up and digital th ermal printer for online record.	The Sterilizer should h ave touch sensitive 7 inch or more LCD colo ur display control system with battery back-up i n both the side of steri liser and digital therm al printer for online re cord.
51	The range of safety features alarm sho uld be audio and visual include over te mperature, pressure sensor failure, phase time-out, pressure relief safet	The range of safety fe atures alarm should b e audio and visual incl ude over temperature,

	y valve, doors not properly closed, power failure if more than 25 seconds, Continuous self-checking of all the safety devices, low water level, water in chamber etc. should be possible after the completion of each cycle.	pressure sensor failure, phase time-out, pressure relief safety valve, doors not properly closed, power failure if more than 10 seconds, Continuous self-checking of all the safety devices, low water level, water in chamber etc. should be possible after the completion of each cycle.
61	1. The sterilizer should confirm the Europe EN 285:2006 standard / AAME ST 8 standard or BIS equivalent standards for Hospital Sterilizers.	1. The sterilizer should confirm to the standards for Hospital Sterilizers ISO 17665-1 or latest .
61	4. The sterilizer should confirm the Medical Device Directive MDD 93/42/EEC amended by Directive 2007/47/EC.	4. The sterilizer should confirm the Medical Device Directive MDD 93/42/EEC amended by Directive 2007/47/EC / MDR Compliant.
	7. The manufacturing company should be bear the ISO 9001:2008.	7. The manufacturing company should be bear the ISO 13485:2016 +A11:2021 or latest
	8. The manufacturing company should be bear the Quality Management System, ISO13683:2003 or ISO 13485:2003 for Medical Devices	Deleted
	9. The manufacturing company should be bear the EN ISO 14001:2004.	Deleted
	The manufacturing firm should have direct operations in India with own trained service set up, engineers to ensure service backup, in time quality services, instant availability of spares or the dealer should have own trained service engineers / technicians to ensure service backup, in time quality services, instant availability of spares	The manufacturing or its Authorised distributor should have direct operations in India with own trained service set up, engineers to ensure service backup, in time quality services, instant availability of spares or the dealer should have own trained service engineers / technicians to ensure

62		service backup, in tim e quality services, inst ant availability of spar es. In case of authoris ed distributor, Manufa ctures undertaking mu st be attached with re gard to compliance of all terms and conditi ons of the tender inclu ding service provision through out the warra nty and CMC period , i ncase of change in aut horised distributors /a uthorised distributor f ailed to provide servic es as per the terms an d conditions .
65	The Sterilizer should have electronic water saving control or eco water re circulation system for external coolin g condenser for condensing the exha ust chamber steam to acceptable te mperature to reuse in the internal s ystem & ensure the quoted system should be a least water consumptio n model & specify the water consumpti on	The Sterilizer should have electronic water saving control or eco water recirculation sy stem for external co oling condenser for c ondensing the exhaus t chamber steam to ac ceptable temperature to reuse in the internal system & ensure the q uoted system should be a least water consu mption model & spec ify the water consum ption ,Bidder need t o-do necessary arrangement for the s ame.
70. 2	5.The equipment complies with the requirement of the Medical Device D irective of class I equipment and Electromagnetic compatibility; all s upporting documents must be provided .	5.The equipment co mplies with the requ irement of the Medic al Device Directive of class I equipment , MDR compliant and Electromagnetic comp atibility; all supporting documents must be pr ovided.
	2.Standards, Safety and Training	
	1.Should be Europe EN 285:2006 stand ard / AAME ST 8 standard or BIS equiva	1.Should be AAMI /ANS I/European CE /US FDA

	lent standards	/ BIS Pressure standards /CDSCO standards/ ISO 17665-1 or latest
	Electrical safety conforms to standards for electrical safety IEC 60601- 1 (Or equivalent International / National standard) general requirement for Electrical safety of Medical equipment.	Electrical safety conforms to standards for electrical safety IEC 60601- 1 or latest (Or equivalent International / National standard) general requirement for Electrical safety of Medical equipment.
	Technical Specification for Washer disinfector minimum 12DIN or more with accessories	
	Data interface RS232 should be available.	Data interface RS232/LAN /USB port/ Wifi /Bluetooth should be available.
	The washer should have 3 dosing pump (detergent, alkaline & lubrication) for process chemicals, instrument lubricants/ enzymatic cleaners.	The washer should have 3 dosing pump (detergent, alkaline & lubrication) for process chemicals, instrument lubricants/ enzymatic cleaners with facility of automatic dosing to ensure consistent detergent dilution without overdosing
	Disinfection with hot water (85C)	Disinfection with hot water (90 deg C)
	Electronic adjustment of water level.	Electronic adjustment of water level with dynamic water filling option asper the load
	The washer disinfector shall be supplied with universal rack, minimum 4 level racks for instrument tray, full size instrument tray as well as stop valves, anti-suction device and plastic water trap.	The washer disinfector shall be supplied with universal rack, minimum 6 level racks for instrument tray, full size instrument tray as well as stop valves, anti-suction device and plastic water trap.

	Technical Specification for Drying cabinet -2nos	
	The Dying Cabinet should be ISO & European CE/US FDA certified.	The Dying Cabinet should be ISO & European CE/US FDA /CDSCO certified.
	Should have indirect UV air treatment during whole cycle.	Should have indirect UV air treatment or should have in built electric precipitator (electrostatic filter) for cleaning of the incoming air. during whole cycle.
	The drying cabinet should have HEPA filtration on drying circuit and also should have monitoring of HEPA filters and indicators when replacement required.	The drying cabinet should have HEPA filtration on drying circuit and also should have monitoring of HEPA filters and indicators when replacement required or should have in built electric precipitator (electrostatic filter) for cleaning of the incoming air.
	600 - 700 litre chamber capacity.	300± 3% litre chamber capacity.
	Technical Specification for Automated Heat Sealing Machine-2nos	
	The warm-up time should not exceed 30 seconds, and the feed speed should be approx. 10 m/min.	The warm-up time should not exceed 180 seconds, and the feed speed should be approx. 10 m/min.
	CSSD equipment monitoring software & computer systems	
	It should allow the user to monitor using a Computer/ Tablet real time status and sterilization linked parameters (temperature, pressure, cycle time, steam saturation, etc) of steam sterlizer and washer disinfector including numeric and pictorial data of all indicator (physic	It should allow the user to monitor using a computer /Tablet real time status and sterilization linked parameters (temperature, pressure, cycle time

	al, biological, chemical, etc) results. There should be a visual dashboard displaying the above parameters on a real time basis and historical trend analysis/ logs as per requirement for a minimum of past 3 years. It should also be possible to print the data including trend analysis for these parameters if required. There should be a facility for the user to remotely login and view the said data if required.	, steam saturation, ets) of steam sterilizer and washer disinfector including post-process result (pass/fail) all indicator (physical, biological, chemical, etc) results. There should be a visual dashboard displaying the above parameters on a real time basis and historical trend analysis / logs as per requirement for a minimum of past 3 years. It should also be possible to print the data including trend analysis for these parameters if required. There should be a facility for the user to remotely login and view the said data if required and if permissible by hospital IT policy.
	The system should be able to log steam sterlizer and washer disinfector uptime/downtime and should enable fault detection for easy trouble shooting.	The system should be able to log Steam Sterilizer and Washer Disinfector uptime/ downtime and should help/ aid fault detection for easy trouble shooting
	8. List of items and suggested manufacturers	
	vi. FURNITURE - Hermen Miller , Godrej , Featherlite, Wipro	vi. FURNITURE - Hermen Miller , Godrej , Featherlite, Wipro,Nilkamal/ Equivalent brand with BIFMA certification
	22.Documentation:	
	3. Cost of spare parts, consumables and accessories(Gasket,PM kit for aal the systems etc...) which are not covered under warranty & CMC period has t	3. Cost of consumables and accessories(Gasket,PM kit for all the systems etc

	o quote in schedule XI as percentage v alue in the Technical Bid, or else will b e consider to be coveras FOC throu ghout the warranty & CMC period.	) which are not covere d under warranty & C MC period has to quot e in ATC 1 & financial document as percent age value Of the final price quoted for the sa me item in the price bi d BOQ , or else will be consider to be cove r as FOC(Free of Cost) throughout the war ranty & CMC period. Spares must be includ ed in the warranty & C MC
	***All the items to be quoted as per price bid BOQ and fur niture as per the BOQ CSSD- RCC NEIGRIHMS**	

–
.

2. Buyer uploaded ATC document Click here to view the file.

Disclaimer

The additional terms and conditions have been incorporated by the Buyer after approval of the Competent Authority Buyer Organization, whereby Buyer organization is solely responsible for the impact of these clauses on the bidding process, its outcome, and consequences thereof including any eccentricity / restriction arising in the bidding process to these ATCs and due to modification of technical specifications and / or terms and conditions governing the bid. If clause(s) is / are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as n and void and such bids may be cancelled by GeM at any stage of bidding process without any notice:-

1. Definition of Class I and Class II suppliers in the bid not in line with the extant Order / Office Memorandum issu DPIIT in this regard.
2. Seeking EMD submission from bidder(s), including via Additional Terms & Conditions, in contravention to exemption provided to such sellers under GeM GTC.
3. Publishing Custom / BOQ bids for items for which regular GeM categories are available without any Category i bunched with it.
4. Creating BoQ bid for single item.
5. Mentioning specific Brand or Make or Model or Manufacturer or Dealer name.
6. Mandating submission of documents in physical form as a pre-requisite to qualify bidders.
7. Floating / creation of work contracts as Custom Bids in Services.
8. Seeking sample with bid or approval of samples during bid evaluation process. (However, in bids for attached categories, trials are allowed as per approved procurement policy of the buyer nodal Ministries)
9. Mandating foreign / international certifications even in case of existence of Indian Standards without specifyir equivalent Indian Certification / standards.
10. Seeking experience from specific organization / department / institute only or from foreign / export experienc
11. Creating bid for items from irrelevant categories.
12. Incorporating any clause against the MSME policy and Preference to Make in India Policy.
13. Reference of conditions published on any external site or reference to external documents/clauses.
14. Asking for any Tender fee / Bid Participation fee / Auction fee in case of Bids / Forward Auction, as the case m

Further, if any seller has any objection/grievance against these additional clauses or otherwise on any aspect of this they can raise their representation against the same by using the Representation window provided in the bid details

in Seller dashboard after logging in as a seller within 4 days of bid publication on GeM. Buyer is duty bound to reply t
such representations and would not be allowed to open bids if he fails to reply to such representations.

*This document shall overwrite all previous versions of Bid Specific Additional Terms and Conditions.

This Bid is also governed by the General Terms and Conditions