HSCC/SES/CSSD/LHMC/2022 Date: 24.01.2023

All Bidders

Amendment-VIII

Subject: Execution including Supply, Installation, Testing & Commissioning of CSSD at LHMC-New Delhi.

Tender No: HSCC/SES/CSSD/LHMC/2022 Date: 27.10.2022

This has reference to above tender.

The following Amendment may be noted which shall be treated as part of the tender document and to be submitted duly signed & stamp along with tender.

Sr. No.	Bidder's Queries	Reply
1.	We have attached the factsheet published by the European Commission which clearly states on Page 2 that "To avoid market disruption and allow a smooth transition from the Directives to the Regulation, several transitional provisions are in place (Article 120). Some devices with certificates issued under the Directives (AIMDD/MDD certificates) may continue to be placed on the market until 26 May 2024, and made available until 26 May 2025. During the transition phase, products certified under the Directives and products certified under the Regulation will coexist on the market. Both will have equal status under the law, and no discrimination on eligibility criteria in public tenders may take place." Then on Page 5 it is mentioned: AIMDD/MDD certificates will generally remain valid until their indicated expiry dates. This applies to all the certificates commonly issued by Notified Bodies, including the EC Design Examination Certificates, Certificates of Conformity, EC Type Examination Certificates, the EC Certificate Full Quality Assurance System, and the EC Certificate Production Quality Assurance. You have replied to our query without proper due diligence on your part. Therefore, we request you to make the	"BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745

	following amendment : ‘’BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745” should be read as “BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745 OR BIS/ European CE Certified by a four digit notified body as per Medical Device Directive 93/42/EEC”	
2.	We have attached the factsheet published by the European Commission which clearly states on Page 2 that “To avoid market disruption and allow a smooth transition from the Directives to the Regulation, several transitional provisions are in place (Article 120). Some devices with certificates issued under the Directives (AIMDD/MDD certificates) may continue to be placed on the market until 26 May 2024, and made available until 26 May 2025. During the transition phase, products certified under the Directives and products certified under the Regulation will coexist on the market. Both will have equal status under the law, and no discrimination on eligibility criteria in public tenders may take place.” Then on Page 5 it is mentioned: AIMDD/MDD certificates will generally remain valid until their indicated expiry dates. This applies to all the certificates commonly issued by Notified Bodies, including the EC Design Examination Certificates, Certificates of Conformity, EC Type Examination Certificates, the EC Certificate Full Quality Assurance System, and the EC Certificate Production Quality Assurance. You have replied to our query without proper due diligence on your part. Therefore, we request you to make the following amendment : ‘’BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745” should be read as “BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745 OR BIS/ European CE Certified by a four digit notified body as per Medical Device	“BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745

	Directive 93/42/EEC"	
3.	We have attached the factsheet published by the European Commission which clearly states on Page 2 that "To avoid market disruption and allow a smooth transition from the Directives to the Regulation, several transitional provisions are in place (Article 120). Some devices with certificates issued under the Directives (AIMDD/MDD certificates) may continue to be placed on the market until 26 May 2024, and made available until 26 May 2025. During the transition phase, products certified under the Directives and products certified under the Regulation will coexist on the market. Both will have equal status under the law, and no discrimination on eligibility criteria in public tenders may take place." Then on Page 5 it is mentioned: AIMDD/MDD certificates will generally remain valid until their indicated expiry dates. This applies to all the certificates commonly issued by Notified Bodies, including the EC Design Examination Certificates, Certificates of Conformity, EC Type Examination Certificates, the EC Certificate Full Quality Assurance System, and the EC Certificate Production Quality Assurance. You have replied to our query without proper due diligence on your part. Therefore, we request you to make the following amendment : ''BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745" should be read as "BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745 OR BIS/ European CE Certified by a four digit notified body as per Medical Device Directive 93/42/EEC"	"BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745
4.	5. Low Temperature Plasma Sterilizer (Pg. 8) Tender terms and condition prevail Amendment Request: A wider range should be given	Tender terms and conditions prevail

	to bidders and to be amended as: "Operational volume 100 – 175 Liters" Amendment Request; Please note that by this you are only promoting monopoly and you will only receive one single bid for this tender. Please refer to the specifications and subsequent amendments published in AIIMS Rae bareli Tender Ref No. HSCC/SES/CSSD/AIIMS/Raebareli/2020 Dated: 15th September 2020. Please Explain why you are changing specifications just to discriminate other bidders. You are requested to amend the following to promote more participation : 5. Low Temperature Plasma Sterilizer (Pg. 8) Operational volume 100 Liters or More	
5.	Please note that by this you are only promoting monopoly and you will only receive one single bid for this tender. Please refer to the specifications and subsequent amendments published in AIIMS Rae bareli Tender Ref No. HSCC/SES/CSSD/AIIMS/Raebareli/2020 Dated: 15th September 2020. This feature is a monopoly and a very biased clause. No reputed manufacturer in USA, Europe or India will be able to comply with this. For efficient plasma sterilization, a concentration of "58-60%" is enough to achieve low temperature sterilization as per norms. THIS CLAUSE HAS NEVER BEEN PUBLISHED IN ANY HSCC TENDER BEFORE. Please Explain why you are changing specifications just to discriminate other bidders. Please Amend this to: i) The Unit should work on H2O2 Concentration from 58% to 60%.	Low Temperature Plasma Sterilizer The unit should have facility to increase H2O2 contraction from 59% to upto 90% or above to increase the speed and efficacy of the sterilization process
6.	We don't know under whose influence are you writing this reply without understanding the need and requirements.	Formalin Injection: The sterilizing agent for low temperature cycles should be stored in liquid state in a single dose bottle. The concentration

	Plasma Sterilizer asked in the tender is also for heat labile medical devices only. We don't understand for what reason you need a different technology for the same use that causes CANCER. This has never been put in any tenders before. Please note that by this you are only promoting monopoly and you will only receive one single bid for this tender. Firstly, We want the item should be DELETED for HUMAN SAFETY. Also, explain us why all equipment's you require should be European CE Certified by a Notified Body but shockingly for LTSF there is no certification in the tender and in this you are mentioning CE as per Medical Device Directive whereas in the other equipment's you are mentioning MDR. This is a clear case of discrimination and promoting bid rigging. This is nothing but a huge eyewash and promotion of monopolization. There is no point in spending ex-chequer money on two different technologies for the same use and that too on an obsolete technology. OR Amend it within safety limits: Formalin Injection: The sterilizing agent for low temperature cycles should be stored in liquid state in a single dose bottle. The concentration of formalin solution should be 2% or more. Also add: The Equipment should be European CE Certified from a four digit notified body.	of formalin solution should be 2% or more.
7.	3. TABLE TOP STERILIZER c) Chamber Size: The sterilizer should have rectangular chamber with approx. dimensions 220 X 200 X 345 mm. for maximum processing capacity per charge. Amendment request: Kindly allow both rectangular and circular chambers and omit approx.	TABLE TOP STERILIZER c) Chamber Size: The sterilizer should have rectangular chamber with approx. dimensions 220 X 200 X 345 mm. for maximum processing capacity per charge.

	chamber dimensions for wider participation and preventing manufacturer-specific dimensions Mentioning specific sizes and promoting only one type of chamber is monopolistic and will lead to only single bid in this tender. We don't understand why the department has ignored its previous tenders while floating this tender. Please refer to the specifications and subsequent amendments published in AIIMS Raebareli Tender Ref No. HSCC/SES/CSSD/AIIMS/Raebareli/2020 Dated: 15th September 2020.	
8.	3. TABLE TOP STERILIZER e) Quality Standards: Sterilizer should comply with the quality standards of Medical Device Directive (MDD), EN 13060 or US FDA/BIS. Amendment request: Please clearly mention certification. "Medical Device Directive (MDD)" should be mentioned as "MDR European CE issued by a four-digit notified body as per (EU) n.2017/745 OR European CE Certified by a four digit notified body as per Medical Device Directive 93/42/EEC" Very cleverly every equipment is specified with different specifications. Please tell us what is the reason that in many equipment's you are not even mentioning certifications. This clearly shows it is done for promoting products of one single company. You are requested to make the following amendment.	TABLE TOP STERILIZER "BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745
9.	3. TABLE TOP STERILIZER	TABLE TOP STERILIZER f) Types of Cycles Process: Table

	f) Types of Cycles Process: Table Top Sterilizer should be equipped with B process, N-process as per latest EN 13060. Proof of declaration of conformity. Amendment request: f) Types of Cycles Process: Table Top Sterilizer should be equipped with B process OR N-process as per latest EN 13060. Proof of declaration of conformity. Kindly provide option to bidder to quote Class B or Class N autoclave. Sterilizers are either categorized as Class B OR Class N. The primary difference between Class B and Class N autoclaves is how they remove air from the chamber prior to sterilization. Class B autoclaves utilize a vacuum pump to completely remove air from the chamber, which enables steam to better penetrate the load. Class N autoclaves use steam from a boiler or generator to create downward displacement, which pushes air out of the chamber. Please refer to the specifications and subsequent amendments published in AIIMS Rae bareli Tender Ref No. HSCC/SES/CSSD/AIIMS/Raebareli/2020 Dated: 15th September 2020. You have already made changes in the past to this clause.	Top Sterilizer should be equipped with B process, N-process as per latest EN 13060. Proof of declaration of conformity.
10.	3. TABLE TOP STERILIZER Chamber: ● should be made of S.S.316Ti & should comply the Pressure Equipment Directive (PED) & EN 13445 norms.	Chamber should be made of S.S.316Ti/ SS 316 & should comply the Pressure Equipment Directive (PED) & EN 13445 norms.

	Amendment request: Chamber: ● should be made of S.S.316Ti/AISI304 & should comply the Pressure Equipment Directive (PED) & EN 13445 norms. Kindly allow AISI304 chamber for wider participation preventing manufacturerspecific conditions. Please refer to the specifications and subsequent amendments published in AIIMS Rae bareli Tender Ref No. HSCC/SES/CSSD/AIIMS/Raebareli/2020 Dated: 15th September 2020. You have already made changes in the past to this clause.	
11.	3. TABLE TOP STERILIZER m) Control Panel: The control system should be microprocessor-based PLC system specially designed for sterilization applications. The control system should have CPU processor with battery back-up, Digital input/output controls, analogue measuring inputs & COM ports for printer & PC connectivity. Amendment Request : m) Control Panel: The control system should be microprocessor-based PLC system specially designed for sterilization applications. The control system should have CPU processor with battery back-up, Digital input/output controls, analogue measuring inputs & COM ports for printer & PC connectivity/ SD card system that ensures recording and storage of all cycles which can then be downloaded on your PC for their management and periodic software updates.	3. TABLE TOP STERILIZER m) Control Panel: The control system should be microprocessor-based PLC system specially designed for sterilization applications. The control system should have CPU processor with battery back-up, Digital input/output controls, analogue measuring inputs & COM ports for printer & PC connectivity/ SD card system that ensures recording and storage of all cycles which can then be downloaded on your PC for their management and periodic software updates.

	Kindly allow SD card system that ensures recording and storage of all cycles which can then be downloaded on your PC for their management. Please refer to the specifications and subsequent amendments published in AIIMS Rae bareli Tender Ref No. HSCC/SES/CSSD/AIIMS/Raebareli/2020 Dated: 15th September 2020. You have already made changes in the past to this clause.	
12.	7. Ultrasonic Cleaner 40 to 50 Litres h) Ultrasonic cleaner should be European CE /US FDA/BIS certified. Amendment Request: h) Ultrasonic cleaner should be European CE declaration of conformity/US FDA/BIS certified. This clause should be amended to prevent manufacturer-specific conditions. Majority of European manufacturers do not possess European CE for Ultrasonic Cleaner because it is not considered a Medical Device as per classification rules of the latest regulations or previous directives. Usually, a declaration of conformity is enough for quality certification of this product. If reference is made to recent HITES tender of AIIMS HITES/PCD/AIIMS-IV/53/CSSD/22-23, it will be clear that this clause is restrictive in nature. Also, Please refer to the specifications and subsequent amendments published in AIIMS Rae bareli Tender Ref No. HSCC/SES/CSSD/AIIMS/Raebareli/2020 Dated: 15th September 2020. You have already made changes in the past to this clause.	Ultrasonic Cleaner 40 to 50 Litres h) Ultrasonic cleaner should be European CE /US FDA/BIS certified.

All other terms & conditions remain unchanged.

Sd/-
Director, LHMC, New Delhi