

All Bidders

Amendment-XI

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.	Bidders' Queries	Reply
1.	<p>As per Amendment -VIII</p> <p>Page No. 1</p> <p>“BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745</p> <p>Amendment Request:</p> <p>"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”.</p> <p>Remarks</p> <p>It is informed that MDR 2017/745 is new version of MDD 93/42/EEC, only after expiration of validity of (MDD) CE certificate it can be applied for MDR.</p> <p>Kindly refer page no. 89, Article 120, point 2 “Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024”</p> <p>MDD European CE certificates and MDR are equivalent as well as mostly reputed manufacturers follow Medical Device Directive 93/42/EEC and after expired of validity MDD CE certificate manufacturer will eligible for apply</p>	<p>As per Amendment-VIII dated: 24.01.2023.</p>

	<p>of MDR version.</p> <p>M/s CISA Production Srl has supplied CSSD equipment with MDD standard in various prestigious organizations like AIIMS New Delhi, AIIMS Deoghar, AIIMS Bhatinda, AIIMS Nagpur, AIIMS Bilaspur, PWD, CPWD, HITES, HSCC and NBCC etc.</p> <p>It is also informed that BIS standard is ask for washer disinfecter however there is no standard under BIS certification for washer disinfecter.</p> <p>Consider the above facts, bidder neither quote washer disinfecter as per BIS standard nor MDR standard.</p> <p>MDR standard is creating limitation in the tender which is arbitrary nature for competition. Hence requested to kindly amend the point.</p>	
2.	<p>Last Date & Submission of online Bids 8th Feb, 2023 up to 03:00 PM</p> <p>Amendment Request</p> <p>Request for extension for a week.</p> <p>We further request you to kindly extend the bid submission due date for a week due to non - receipt of bank few documents from bank.</p>	<p>Bid submission date is extended till 22.02.2023.</p>

All other terms & conditions remain unchanged.

Sd/-
Director, LHMC, New Delhi