

**Amendment No. 03**

**Sub: Amendment to the referred tender enquiry**

**Ref.: Tender Enquiry No. HITES/PCD/PMSSY-IV/27/CTVS/2022-23 dated 02-Nov-2022 with its Amendment no. 01 dated 14-Dec-2022 and Amendment No. 02 dated 17-Dec-2022.**

Following changes are being incorporated in the tender:

**SECTION - VII**  
**TECHNICAL SPECIFICATION**

Tender spec Para	TENDER SPECIFICATION	READ AS
<b>Sch. No. 01 Intra-Aortic Balloon Pump (IABP)</b>		
3.1	Pneumatics: Drive system: Dual head reciprocating compressor or stepper motor driven bellows Drive gas- Helium (Available with disposable canister or refillable cylinder). Pumping Volume: 0.5 cc-50 cc Counter pulsation rate: 40- 200 pulsations per minute	Pneumatics: Drive system: Dual head reciprocating compressor <b>or scroll compressor</b> or stepper motor driven bellows Drive gas- Helium (Available with disposable canister or refillable cylinder). Pumping Volume: 0.5 cc-50 cc Counter pulsation rate: 40- 200 pulsations per minute
3.16	Should have software which allows the user to monitor the IABP from any remote location via a modem	Should have software which allows the user to monitor the IABP from any remote location via a modem/ <b>HIS connectivity/CPMS</b> connectivity
		<p><b>Added para:</b> Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model.</p> <p>In case the supplier has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced before award of contract.</p>
<b>Sch. No. 02 Cardiopulmonary Bypass Machine</b>		
		<p><b>Added para:</b> Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model.</p> <p>In case the supplier has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced before award of contract.</p>

Response To Pre-Bid Queries				
Sch. No. 01 Intra-Aortic Balloon Pump (IABP)				
Tender spec Para	Tender Specification	Representation Received From Firms	Committee Recommendation	Justification
3.1	Pneumatics: Drive system: Dual head reciprocating compressor or stepper motor driven bellows Drive gas- Helium (Available with disposable canister or refillable cylinder). Pumping Volume: 0.5 cc-50 cc Counter pulsation rate: 40- 200 pulsations per minute	Pneumatics: Drive system: Scroll Compressor Drive gas- Helium (Available with disposable canister or refillable cylinder). Rate: 40- 200 pulsations per minute  Faster compressor speed and more efficient operation at higher heart rates. Helps to optimize diastolic augmentation because balloon can stay inflated longer during diastole	Amended as: Pneumatics: Drive system: Dual head reciprocating compressor <b>or scroll compressor</b> or stepper motor driven bellows Drive gas- Helium (Available with disposable canister or refillable cylinder). Pumping Volume: 0.5 cc-50 cc Counter pulsation rate: 40- 200 pulsations per minute	For wider participation
3.13	Should be capable of removing condensation automatically without user intervention and should be maintenance free.	Should be capable of removing condensation using <b>Nafion Technology</b> automatically without user intervention and should be maintenance free.  No bottle required to collect condensate and no emptying required. Hence no stoppage of therapy or alarms.	No change	
3.16	Should have software which allows the user to monitor the IABP from any remote location via a modem	To be removed  HIS connectivity available. Modem connection technology is outdated	Amended as: Should have software which allows the user to monitor the IABP from any remote location via a modem/ <b>HIS connectivity/ CPMS connectivity</b>	For wider participation
	Suggested by the bidder	Should have two lithium ion batteries with 5 LED lights each to indicate battery charge status.	No change	
	Suggested by the bidder	Should be able to convert to transport mode which is lesser in weight	No change	

Response To Pre-Bid Queries				
Sch. No. 01 Intra-Aortic Balloon Pump (IABP)				
Tender spec Para	Tender Specification	Representation Received From Firms	Committee Recommendation	Justification
	Suggested by the bidder	Should have transport approval from regulatory authority for both road and air transport	No change	
		As per prebid discussion	<p><b>Added para:</b> Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model.</p> <p>In case the supplier has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced before award of contract.</p>	To comply with MDR 2017

Response To Pre-Bid Queries				
Sch. No. 02 Cardiopulmonary Bypass Machine				
Tender spec Para	Tender Specification	Representation Received From Firms	Committee Recommendation	Justification
3.9	Sevoflurane Vapourizer with mixture blender, tubing & holder - 1 no.	Vapouriser is a separate equipment with no relation to Heart Lung machine. It is requested to keep it out of this tender	No change	Bidder has agreed to supply the same during the prebid discussion
BOQ.7	Sevoflurane Vapourizer with mixture blender, tubing & holder 1 No	Vapouriser is a separate equipment with no relation to Heart Lung machine. It is requested to keep it out of this tender	No change	Bidder has agreed to supply the same during the prebid discussion

Response To Pre-Bid Queries				
Sch. No. 02 Cardiopulmonary Bypass Machine				
Tender spec Para	Tender Specification	Representation Received From Firms	Committee Recommendation	Justification
		As per prebid discussion	<p><b>Added para:</b> Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model.</p> <p>In case the supplier has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced before award of contract.</p>	To comply with MDR 2017

**Note:**

- i. Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids.
- ii. All other contents of the tender enquiry including terms & conditions remain unaltered.
- iii. EMD should be valid up to 225 days or more from the date of submission mentioned above.
- iv. **For Tender IDs 2022\_HLL\_133841\_1 and 2022\_HLL\_133841\_2 only:**  
TC compliance sheet v1.0 and Price bid format v1.0 is being uploaded on CPP Portal for necessary actions of interested Bidders.