

**Amendment No. 3**

**Date: 30.12.2023**

**Sub: Amendment No. 03 to the Tender Enquiry Document**

**Ref: (i) Tender Enquiry No.: HITES/PCD/AMCC/RT SERVICE/23-24 dated 08.12.2023**

**Tender Timeline:**

**For:**

<b>Sl. No.</b>	<b>Description</b>	<b>Schedule</b>
c.	Closing date & time for submission of online bids	03-01-2024, 01:00 PM
d.	Closing date & time for submission of <b>tender processing fee and EMD in physical form*</b>	03-01-2024, 02:00 PM
e.	Time and date of opening of online bids	03-01-2024, 02:30 PM
f.	Venue for :- Submission of tender processing fee, EMD in physical form, Tender Opening-Tech Bid	HLL Infra Tech Services Limited, Procurement & Consultancy Services Division, B-14 A, Sector-62, Noida-201307

**Read As:**

<b>Sl. No.</b>	<b>Description</b>	<b>Schedule</b>
c.	Closing date & time for submission of online bids	06-01-2024, 01:00 PM
d.	Closing date & time for submission of <b>tender processing fee and EMD in physical form*</b>	06-01-2024, 02:00 PM
e.	Time and date of opening of online bids	06-01-2024, 02:30 PM
f.	Venue for :- Submission of tender processing fee, EMD in physical form, Tender Opening-Tech Bid	HLL Infra Tech Services Limited, Procurement & Consultancy Services Division, B-14 A, Sector-62, Noida-201307

**SECTION – III  
SPECIAL INSTRUCTIONS TO TENDERERS (SIT)**

**For:**

This bid is reserved for Class I and Class II bidders only as per make in India Policy (DPIIT Order dated 16th September 2020 and its subsequent amendments, issued time to time). Format for relevant “Make in India” authorization certificate is enclosed herewith as Annexure-A. Bidders are requested to submit the duly filled document in support of their claim of being Class I and Class II bidders.

**Read As:**

This bid is reserved for Class I and Class II bidders only as per make in India Policy (DPIIT Order dated 16th September 2020 and its subsequent amendments, issued time to time). Format for relevant “Make in India” authorization certificate is enclosed herewith as Annexure-A, Duly certified by CA. However, Format provided at Annexure-A (in Amendment No. 1) is not mandatory.

**OR**

Alternatively, the bidders can submit a CA certified document, clearly defining Make in India content (%) in the quoted items. Certificate should also have details of “places of value addition” along with respective content addition details (in %).

**SECTION VII**  
**TECHNICAL SPECIFICATIONS**

Medical Gas Pipeline System		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Page 58, Para 4.1	Medical and Surgical Air System (Package Unit) - Tolerance of +/-5% is acceptable on plant flow capacity of 5000 LPM as Primary & 5000 LPM as standby or Total minimum Plant Capacity of 10000LPM Air-cooled <b>oil free</b> compressors for continuous duty application with highest output of compressed air, low power consumption and very low vibration resulting in low noise level.  Air Compressor Modules It should be <b>Oil-Less</b> , noiseless and compact Screw/Scroll Compressors to produce the plant output of 5000 LPM as Primary & 5000 LPM as standby or Total minimum Plant Capacity of 10000LPM	Medical and Surgical Air System (Package Unit) - Tolerance of +/-5% is acceptable on plant flow capacity of 5000 LPM as Primary & 5000 LPM as standby or Total minimum Plant Capacity of 10000LPM Air-cooled <b>oil Less</b> compressors for continuous duty application with highest output of compressed air, low power consumption and very low vibration resulting in low noise level.  Air Compressor Modules It should be <b>Oil-Less</b> , noiseless and compact Screw/Scroll Compressors to produce the plant output of 5000 LPM as Primary & 5000 LPM as standby or Total minimum Plant Capacity of 10000LPM
Page 58, Para 4	Medical and Surgical Air System (Package Unit) Purity should be tested as per the American Pharmacopeia / European Pharmacopeia standard.	May be amended as: Purity should be tested as per the American Pharmacopeia / European Pharmacopeia/ <b>Indian Pharmacopeia standard</b>
Page 70, Para 19	Ceiling Suspended Rigid/Boom Pendant: Maximum numbers of possible services on column should be minimum 30 including gas, electrical and data	Ceiling Suspended Rigid/Boom Pendant: Minimum number of services required on column are 19 nos. and a provision may be provided for 24 total services keeping the additional future requirements. The total number of services required will be finalized by the end user at the time of drawing approval after placement of purchase order.
Page 74	BoQ: 11. Valve Box - 3 Gas Service - 46 Nos 11. Valve Box - 4 Gas Service (Price to be quoted separately) - 1 Nos  12. Medical Gas Area Alarm for 3 services - 46 Nos 12. Medical Gas Area Alarm 4 services - 1 No 12 . Medical Gas Area Alarm 5 services - 0 No	BoQ: 11. Valve Box - 3 Gas Service - 41 Nos 11. Valve Box - 4 Gas Service (Price to be quoted separately) - 5 Nos  12. Medical Gas Area Alarm for 3 services - 41 Nos 12. Medical Gas Area Alarm 4 services - 5 Nos 12 . Medical Gas Area Alarm 5 services -1 No
Page 77,	Annexure-I MGPS MATRIX - AMCC, PGI CHANDIGARH	Revised Annexure- I MGPS MATRIX - AMCC, PGI CHANDIGARH attached herewith

Note:

- Revised MGPS Matrix- AMCC, PGI CHANDIGARH attached as **Annexure-I**.
- Pre-bid technical representation disposals are attached as **Annexure-II**
- Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids.
- All other contents of the tender enquiry including terms & conditions remain unaltered.
- EMD should be valid up to 225 days or more from the techno-Commercial bids opening date.

















## Annexure-II

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
	MGPS	What is the line size for the gas pipeline (i.e. O2, N2O, MA4, MA7, Vacuum, CO2(if required))	Specified in BoQ
		Please Explain the manifold room	As per the tender specification
		Capacity of Air Conditioning to be Installed?	As per the tender specification of MGPS
		Please explain responsibility for the detecting earthing (Chemical Type) for the MGPS Plant Room	As per the tender specification/BoQ
	CDSCO License asked for various items	<p>For most of the MGPS items, it is mentioned in the tender specifications that "it should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted", in this regard we would like to inform you again because we had already informed you many times earlier about the same and it is fact that:</p> <ul style="list-style-type: none"> <li>· After amendments issued for Medical Device Rules 2017, License is not mandatory for devices which are listed under class-A (non-sterile and non-measuring).</li> <li>· Some of other companies have got the license from CDSCO State Licensing Authority because they have applied before the above notification issued by the Government of India.</li> <li>· Would request that HITES should get a clarification / updation from CDSCO Licensing Authorities that whether License is required or not</li> <li>· And companies who have already got issued the CDSCO License, taking undue advantages of these licenses because of departments still asking the license for CDSCO in their tenders inspite of registration under non-regulatory devices due to lack of knowledge about the above notifications.</li> <li>· We had also applied for this license before 3 months but department (CDSCO) has returned our application with the remarks that "Firm has applied for fresh license for items under class A, which falls under the category of non-sterile &amp; non-measurable. No license is required for these products. So firm is directed to get the registration done for these products on Sugam portal" (Copy enclosed for your reference).</li> <li>· Now companies like us facing difficulties to get the license and happening injustice with us and companies who have already got issued the CDSCO License, taking undue advantages of these licenses.</li> </ul> <p>It is just only because of departments has lack of knowledge or have not up-to-dated with the government notifications about MDR and still</p>	No Change

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
		writing "License" word in tenders inspite of "registration under non-regulatory devices". Now, it is a request to HITES authorities to kindly accept our request and also requested for your consideration in future projects / tenders. We hope that you will issue corrigendum for the following including the above points which we have observed in tender documents	
Page 46, Para 10	Bidder shall be responsible for free maintenance of all component of Gas pipeline system during warranty period including all filters & consumables	Bidder shall be responsible for free maintenance of all component of Gas pipeline system during warranty period.  Remarks: Please be informed that usage of filters & consumables completely depends upon the hospital / User requirement and it can't be included in the warranty as this is an unwarranted burden on the bidder, for which price burden can't be put in a tender on assumption basis. We therefore request you to kindly delete the work "Filters and Consumables" from the technical specification	No change
Page 53, Para 1.2	<p><b>Fully Automatic Oxygen Control Panel</b> Automatic control panel should be constructed in accordance with the requirement of international standards. The fully automatic oxygen control panel should comply with HTM 02-01/NFPA 99C/ DIN / EN / ISO-7396-1 standards. It should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted</p>	<p>In accordance with the latest notification from the Government of India (File No. 29/Misc/03/2020-DC (200)), issued by the Directorate General of Health Services, Central Drugs Standard Control Organisation (Medical Device Division), the 'Medical Gas Pipeline System' has been categorized as a Class A product. The notification (ref. no. G.S.R.777(E)), an amendment to the Medical Devices Rules, 2017, explicitly outlines that for Class A non-sterile and non-measuring medical devices, manufacturers are only required to upload information for registration on the Online System for Medical Devices. This process entails the registration of items on the online system without the necessity for a separate license. Kindly amend as under: "It should have import/manufacturing registration with Central licensing Authority or State licensing authority of CDSCO for the product and proof of registration should be submitted." It should have import/manufacturing license / registration from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license / registration should be submitted</p>	No change
Page 54, Para 1.2	The Automatic Control Panel should be installed in such a way to meet the peak flow requirement of the Hospital/Institute	Kindly clarify the quantity of Automatic Control Panels required in the BOQ in order to meet the peak flow requirement	As per the tender specification & BoQ
Page 56, Para 2.1	The control panel should also have heaters to prevent ice formation on the regulators at high flow	N2O Manifold with Control Panel & CO2 Manifold with Control Panel: Heater system is mandatory to prevent ice formation which is not mentioned in the technical specifications. Kindly	Already specified in the tender specification

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
	rates.	advise	
Page 55, Para 2.1	<p>Fully Automatic Nitrous Oxide Control Panel The fully automatic N2O control panel should comply with HTM 02-01/ NFPA 99 C/ EN /DIN /ISO 7396-1 STANDARD. It should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted.</p>	<p>In accordance with the latest notification from the Government of India (File No. 29/Misc/03/2020-DC (200)), issued by the Directorate General of Health Services, Central Drugs Standard Control Organisation (Medical Device Division), the 'Medical Gas Pipeline System' has been categorized as a Class A product. The notification (ref. no. G.S.R.777(E)), an amendment to the Medical Devices Rules, 2017, explicitly outlines that for Class A non-sterile and non-measuring medical devices, manufacturers are only required to upload information for registration on the Online System for Medical Devices. This process entails the registration of items on the online system without the necessity for a separate license. Kindly amend as under: "It should have import/manufacturing registration with Central licensing Authority or State licensing authority of CDSCO for the product and proof of registration should be submitted." It should have import/manufacturing license / registration from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license / registration should be submitted</p>	No change
Page 55, Para 2.1	<p>Fully Automatic Nitrous Oxide Control Panel The Automatic Control Panel should be installed in such a way to meet the peak flow requirement of the Hospital/Institute</p>	<p>Kindly clarify the quantity of Automatic Control Panels required in the BOQ in order to meet the peak flow requirement</p>	As per the tender specification & BoQ
Page 57, Para 3.1	<p>Fully Automatic Entonox (50% N2O + 50% O2) Control Panel The fully automatic Entonox (N2O+O2) - 50%+50% control panel should comply with HTM 02-01/ NFPA 99 C/ EN /DIN /ISO 7396-1 STANDARD. It should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted.</p>	<p>In accordance with the latest notification from the Government of India (File No. 29/Misc/03/2020-DC (200)), issued by the Directorate General of Health Services, Central Drugs Standard Control Organisation (Medical Device Division), the 'Medical Gas Pipeline System' has been categorized as a Class A product. The notification (ref. no. G.S.R.777(E)), an amendment to the Medical Devices Rules, 2017, explicitly outlines that for Class A non-sterile and non-measuring medical devices, manufacturers are only required to upload information for registration on the Online System for Medical Devices. This process entails the registration of items on the online system without the necessity for a separate license. Kindly amend as under: "It should have import/manufacturing registration with Central licensing Authority or State licensing authority of CDSCO for the product and proof of registration should be submitted."</p>	No change

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
		It should have import/manufacturing license / registration from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license / registration should be submitted	
Page 57, Para 3.1	The Automatic Control Panel should be installed in such a way to meet the peak flow requirement of the Hospital/Institute	Kindly clarify the quantity of Automatic Control Panels required in the BOQ in order to meet the peak flow requirement	As per the tender specification & BoQ
Page 58, Para 4.1	<p>Medical and Surgical Air System (Package Unit) - Tolerance of +/-5% is acceptable on plant flow capacity of 5000 LPM as Primary &amp; 5000 LPM as standby or Total minimum Plant Capacity of 10000LPM Air-cooled <b>oil free</b> compressors for continuous duty application with highest output of compressed air, low power consumption and very low vibration resulting in low noise level.</p> <p>Air Compressor Modules It should be <b>Oil-Less</b>, noiseless and compact Screw/Scroll Compressors to produce the plant output of 5000 LPM as Primary &amp; 5000 LPM as standby or Total minimum Plant Capacity of 10000LPM</p>	<p>The terminology regarding compressors can vary, and it's important to use precise terms. In the context of compressors, "Oil-Free" is the more commonly used term instead of "Oil-Less." "Oil-Less" is incorrect, hence, kindly amend to "Oil-Free"</p>	<p>Medical and Surgical Air System (Package Unit) - Tolerance of +/- 5% is acceptable on plant flow capacity of 5000 LPM as Primary &amp; 5000 LPM as standby or Total minimum Plant Capacity of 10000LPM Air-cooled <b>oil Less</b> compressors for continuous duty application with highest output of compressed air, low power consumption and very low vibration resulting in low noise level.</p> <p>Air Compressor Modules It should be <b>Oil-Less</b>, noiseless and compact Screw/Scroll Compressors to produce the plant output of 5000 LPM as Primary &amp; 5000 LPM as standby or Total minimum Plant Capacity of 10000LPM</p>

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
Page 58, Para 4	<p>Medical and Surgical Air System (Package Unit ) It should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted.</p>	<p>Kindly omit the requirement for a CDSCO license. Kindly omit the requirement for a CDSCO license because none of the Original Equipment Manufacturers for Components for Medical and Surgical Air Systems., including well-known companies such as Atlas Copco, Gardner Denver, Ingersoll Rand, Trident Pneumatics, Summits, Solberg etc. possess a CDSCO license. In a previous tender for similar work, we observed instances where companies were quoting items under their brand names or their sister concern, even though they are not the actual manufacturers of components such as Compressor Pumps, Air Receiver Tanks, Filtration Systems, Air Dryers, etc. A packaged unit comprises several components, and it is crucial that the Original Equipment Manufacturer holds a CDSCO registration and not the firm quoting the tender or their sister concern. To ensure the delivery of high-quality products and to streamline the procurement process, we kindly request the omission of the requirement for a CDSCO license for Medical and Surgical Air Systems</p> <p>It should have import/manufacturing license / registration from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license / registration should be submitted</p>	No change
Page 58, Para 4	<p>Medical and Surgical Air System (Package Unit ) Purity should be tested as per the American Pharmacopeia / European Pharmacopeia standard.</p>	<p>Kindly amend as under:  “Purity should be tested as per the American Pharmacopeia / European Pharmacopeia/<b>Indian Pharmacopeia standard.</b>”  As we prioritize Make in India products, please ensure the inclusion of adherence to the Indian Pharmacopeia standards</p>	<p>May be amended as:  Purity should be tested as per the American Pharmacopeia / European Pharmacopeia/<b>Indian Pharmacopeia standard</b></p>
Page 61, Para 5	<p>VACUUM SYSTEMS (Package unit) - Tolerance of +/-5% is acceptable in plant flow capacity of 6000 LPM as primary and 6000 LPM as standby. It should comply with HTM 0201/ NFPA 99 C / EN /DIN/ISO 7396-1 It should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted.</p>	<p>Kindly omit the requirement for a CDSCO license because none of the Original Equipment Manufacturers of Components for Vacuum System, including well-known companies such as Atlas Copco, Busch, Gardner Denver, Ingersoll Rand, Trident Pneumatics, Summits, Solberg etc. possess a CDSCO license. In a previous tender for similar work, we observed instances where companies were quoting items under their brand names or their sister concern, even though they are not the actual manufacturers of components such as Vacuum Pumps, Vacuum Receiver Tank, Bacterial Filtration System, etc. A packaged unit comprises several components, and it is crucial that the Original Equipment Manufacturer holds a CDSCO registration and not the firm quoting the</p>	No change

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
		<p>tender or their sister concern. To ensure the delivery of highquality products and to streamline the procurement process, we kindly request the omission of the requirement for a CDSCO license for Medical and Surgical Air Systems</p> <p>It should have import/manufacturing license / registration from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license / registration should be submitted</p>	
Page 63, Para 6A	<p>6A Low flow ward vacuum unit - (Price should be quoted separately and freed for 3 years from the date of NOA) Should provide digital flow meters with fine control (analogue type will not be accepted)</p>	<p>Technical specifications of Ward Vacuum Unit may please be followed: Analog/ digital Low Flow Vacuum Unit may please be allowed.</p> <p>Remarks: The technical specification of Low Flow Ward Vacuum Unit seems to company specific and may please be deleted. Why only digital Low flow vacuum unit is preferred, when indigenous ward vacuum unit comes with analogue display. Please amend to digital / Analog display for low flow.</p>	No change
Page 64, Para 8	<p>AGSS (Anesthetic Gas Scavenging System) Plant - Anesthetic Gas Scavenging System (AGSS) of minimum 1000LPM as Primary &amp; 1000LPM as Standby,It should comply with HTM 02-01/ NFPA 99 C/EN/ISO 7396-1. It should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted.</p>	<p>It should have import/manufacturing license / registration from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license / registration should be submitted</p>	No change

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
Page 66, Para 10	<p>GAS OUTLETS with Probes It should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted.</p>	<p>In accordance with the latest notification from the Government of India (File No. 29/Misc/03/2020-DC (200)), issued by the Directorate General of Health Services, Central Drugs Standard Control Organisation (Medical Device Division), the 'Medical Gas Pipeline System' has been categorized as a Class A product. The notification (ref. no. G.S.R.777(E)), an amendment to the Medical Devices Rules, 2017, explicitly outlines that for Class A non-sterile and non-measuring medical devices, manufacturers are only required to upload information for registration on the Online System for Medical Devices. This process entails the registration of items on the online system without the necessity for a separate license. Kindly amend as under: "It should have import/manufacturing registration with Central licensing Authority or State licensing authority of CDSCO for the product and proof of registration should be submitted." It should have import/manufacturing license / registration from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license / registration should be submitted</p>	No change
Page 67, Para 12	<p>Master Alarm (Digital) It should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted</p>	<p>In accordance with the latest notification from the Government of India (File No. 29/Misc/03/2020-DC (200)), issued by the Directorate General of Health Services, Central Drugs Standard Control Organisation (Medical Device Division), the 'Medical Gas Pipeline System' has been categorized as a Class A product. The notification (ref. no. G.S.R.777(E)), an amendment to the Medical Devices Rules, 2017, explicitly outlines that for Class A non-sterile and non-measuring medical devices, manufacturers are only required to upload information for registration on the Online System for Medical Devices. This process entails the registration of items on the online system without the necessity for a separate license. Kindly amend as under: "It should have import/manufacturing registration with Central licensing Authority or State licensing authority of CDSCO for the product and proof of registration should be submitted."</p>	No change



Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
Page 68, Para 12	<p>Medical Gas Area Alarm</p> <p>The medical gas central alarms should be capable of monitoring up to 6 medical gas services (As specified in BOQ of respective institute) by means of pressure sensors which detect deviations from the normal operating limits of either pressure or medical vacuum. The area alarm should have a digital display of pressures. The medical gas area alarm should fully satisfy the HTM 02-01/ NFPA 99 C/EN/DIN/ISO 7396-1 requirements and It should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted</p>	<p>In accordance with the latest notification from the Government of India (File No. 29/Misc/03/2020-DC (200)), issued by the Directorate General of Health Services, Central Drugs Standard Control Organisation (Medical Device Division), the 'Medical Gas Pipeline System' has been categorized as a Class A product. The notification (ref. no. G.S.R.777(E)), an amendment to the Medical Devices Rules, 2017, explicitly outlines that for Class A non-sterile and non-measuring medical devices, manufacturers are only required to upload information for registration on the Online System for Medical Devices. This process entails the registration of items on the online system without the necessity for a separate license.</p> <p>Kindly amend as under: "It should have import/manufacturing registration with Central licensing Authority or State licensing authority of CDSCO for the product and proof of registration should be submitted."</p> <hr/> <p>It should have import/manufacturing license / registration from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license / registration should be submitted</p>	No change
Page 70, Para 19	<p>Ceiling Suspended Rigid/Boom Pendant:</p> <p>Medical gas hoses shall be compliant to ISO 5359:2009 color coded throughout its length and identified gas type marked every 200 mm repeated contain no plasticizer. Anti static material with a surface resistivity of 1.1E11/L/sq. and a slow release anti bacterial agent resistant to MRSA, listeria and Pseudomonas species.</p>	<p>Please standardize the technical specifications for the Medical Gas Hoses. It has been observed that, for the same Item Sr. No. 20 in the technical specifications, there is inconsistency in the stated specifications.</p> <p>Kindly amend as under in accordance to technical specifications of Item Sr. No. 20: "It should be colour coded for individual services i.e. white for Oxygen, Blue for N2O and Yellow for Vacuum, Black for air. Antistatic rubber tube should be as per ISO standards. It should be CE certified /BIS certified / from ISO 13485 certified manufacturer."</p>	No change
Page 70, Para 19	<p>Ceiling Suspended Rigid/Boom Pendant:</p> <p>Maximum numbers of possible services on column should be minimum 30 including gas, electrical and data</p>	<p>Maximum numbers of possible services on column should be minimum 19 - 20 including gas, electrical and data.</p> <p>Remarks: At row no. 12, you have asked for 19 services only, however here 30 services are mentioned, which needs to be corrected. Kindly consider the same for amendment</p>	As per the current specification the services required are 19 nos. and a provision may be provided for 24 total services keeping the additional future requirements. The total number of services required will be finalized by the end user at the time of drawing approval after

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
			placement of purchase order.
Page 70, Para 19	Ceiling Suspended Rigid/Boom Pendant: It should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted	<p>In accordance with the latest notification from the Government of India (File No. 29/Misc/03/2020-DC (200)), issued by the Directorate General of Health Services, Central Drugs Standard Control Organisation (Medical Device Division), the 'Medical Gas Pipeline System' has been categorized as a Class A product. The notification (ref. no. G.S.R.777(E)), an amendment to the Medical Devices Rules, 2017, explicitly outlines that for Class A non-sterile and non-measuring medical devices, manufacturers are only required to upload information for registration on the Online System for Medical Devices. This process entails the registration of items on the online system without the necessity for a separate license.</p> <p>Kindly amend as under: "It should have import/manufacturing registration with Central licensing Authority or State licensing authority of CDSCO for the product and proof of registration should be submitted."</p> <p>It should have import/manufacturing license / registration from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license / registration should be submitted</p>	No change
Page 71, Para 19	CARBON DIOXIDE SYSTEM (Price should be quoted separately and the same will be considered for price evaluation) The system should consist of medical CO2 Manifold 4 + 4 Primary & 2+2 Standby with Class-D type Cylinders (12 Nos over and above than BOQ quantity of CO2 cylinders) and control panel . Control panel of CO2 should have import/ manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted	<p>In accordance with the latest notification from the Government of India (File No. 29/Misc/03/2020-DC (200)), issued by the Directorate General of Health Services, Central Drugs Standard Control Organisation (Medical Device Division), the 'Medical Gas Pipeline System' has been categorized as a Class A product. The notification (ref. no. G.S.R.777(E)), an amendment to the Medical Devices Rules, 2017, explicitly outlines that for Class A non-sterile and non-measuring medical devices, manufacturers are only required to upload information for registration on the Online System for Medical Devices. This process entails the registration of items on the online system without the necessity for a separate license.</p> <p>Kindly amend as under: "It should have import/manufacturing registration with Central licensing Authority or State licensing authority of CDSCO for the product and proof of registration should be submitted."</p> <p>It should have import/manufacturing license / registration from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license / registration should be submitted</p>	No change

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
Page 72, Para 24	Extra Works (Price should be quoted separately and the same will be considered for price evaluation)	<p>Extra work prices should not be considered in the total price and should not be covered for L1 ranking</p> <p>Remarks:Extra item unit rates must not be covered under total price as bidders may take undue advantage and quote lesser price to get the work as the work of extra item is not mandatorily covered under the said tender contract</p>	No change
Page 74, Para BoQ 11	11 AREA VALVE BOX (WITHOUT VALVES): Supply,Installation, testing and commissioning of Area Valve Boxes. as per specification	<p>BOQ MGPS System- AMCC, PGIMER Chandigarh (Item. No:11): Area Valve Box (without Valves): BOQ mentions Area Valve Box without valves. As per HTM guidelines, valves need to be pre fitted with Area Valve Box. Kindly advise. Area Valve box with inbuilt Area Alarm will reduce space consumption and would have an elegant design.</p>	No change
Page 77,	Annexure-I MGPS MATRIX - AMCC, PGI CHANDIGARH	<p>MGPS Matrix- AMCC, PGI Chandigarh (Annexure-1): AVSU &amp; Alarm Gas Services does not match with the Gas outlet point services. Some are mentioned below: 1) Ground Floor: Block A: Emergency procedure/ delivery room: Oxygen/ MA4/ Vacuum &amp; N2O Gas outlet points requires AVSU &amp; Alarm 4 gas service. Matrix mentioned is for AVSU 3 gas service. 2) Ground Floor: Block A: SLR Emergency Bed: Oxygen/ MA4/ Vacuum &amp; Entonox Gas outlet points requires AVSU &amp; Alarm 4 gas service. Matrix mentioned is for AVSU 3 gas service. 3) First Floor: Block A: HDU: Oxygen/ MA4/ Vacuum &amp; Entonox Gas outlet points requires AVSU &amp; Alarm 4 gas service. Matrix mentioned is for AVSU 3 gas service. 4) First Floor: Block A: Labour delivery room: Oxygen/ MA4/ Vacuum &amp; Entonox Gas outlet points requires AVSU &amp; Alarm 4 gas service. Matrix mentioned is for AVSU 3 gas service. 5) First Floor: Block A: Labour delivery room: Oxygen/ MA4/ Vacuum &amp; Entonox Gas outlet points requires AVSU &amp; Alarm 4 gas service. Matrix mentioned is for AVSU 3 gas service. The above mentioned are a few mismatches in the MGPS matrix. Kindly advise.</p>	<p>Revised Annexure attached</p> <p>BoQ: 11. Valve Box - 3 Gas Service - 41 Nos 11. Valve Box - 4 Gas Service (Price to be quoted separately) - 5 Nos</p> <p>12. Medical Gas Area Alarm for 3 services - 41 Nos 12. Medical Gas Area Alarm 4 services 5 Nos 12. Medical Gas Area Alarm 5 services -1 No</p>
		<p>Make list: Indian make/ Imported: Kindly advise/ specify, Indian / Imported as both have an entirely different budget range. Hence, we requested to clarify Indian or European CE with 4 digit notified body number which standard is required for this project</p>	Bidders have to quote meeting the tender specification

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
	<p>1.5 Oxygen Flow meter with Humidifier Bottle (For Adults)</p> <p>1.6 Oxygen Flow meter with Humidifier Bottle (Neonates)</p> <p>18 Horizontal /Vertical Bed Head Panel</p>	<p>It Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the quoted model and copy of valid license should be submitted.</p> <p>We request you to kindly maintain that import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the quoted model and copy of valid license should be submitted.</p> <p>We also wish to inform that as per classification of Medical Devices issued by CDSCO; Medical Gas Pipeline System falls under Category A for which license is required for items that are Sterile and Measuring. A Notification from Central Drugs Standard Control Organisation Government of India Ministry of Health and Family Welfare, FDA Bhawan, New Delhi Dated 30th September, 2022 is enclosed herewith at Page 1 for your ready reference.</p> <p>The Central Drugs Standard Control Organization (CDSCO) is the regulatory body in India responsible for the registration and regulation of medical devices. In order to manufacture medical devices in India, companies must obtain a manufacturing license from CDSCO.</p> <p>Whereas, item 1.5 Oxygen Flow meter with Humidifier Bottle (For Adults); Item 1.6 Oxygen Flow meter with Humidifier Bottle (Neonates); 18 Horizontal /Vertical Bed Head Panel are not mentioned for import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the quoted model and copy of valid license should be submitted. We request CDSCO licencing should be mentioned for these 3 items also.</p> <p>As this is Govt. of India, CDSCO guidelines, it is mandatory for all and same is conveyed by HITES in the pre-bid meeting.</p>	<p>No change</p>

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
	<p>The Medical Gas Pipeline System must follow Single Standard any one only from NFPA99c/HTM 02-01/ISO 7396-1/DIN/EN except Copper Pipe for AGSS Ventury type is not acceptable.</p> <p>a. Control Panels &amp; Manifold for O2, N2O &amp; CO2  b. Flowmeter with humidifer bottle  c. Medical and Surgical Air System  d. Medical Vacuum System  e. Ward Vacuum Unit  f. Theatre Vaccum Unit  g. AGSS Plant  h. All types Outlets  i. AVSU  j. Area &amp; Master Alarm  k. Line Isolation valves  l. High Pressure tubes  m. Bed Head Panel</p>	<p>Medical Gas Pipeline System is life saving system. Be it a new-born baby receives oxygen, be it a patient anaesthetized for an operation. The life of a person depends on safe, reliable functioning and constant supply of medical gas. Therefore it is requested for better synchronisation, designing, manufacturing according to highest quality standards, installation and maintenace purpose; we request all the mentioned MGPS items except copper pipes should be proccured from same principal company/manufacturer.</p> <p>Earlier, in most of the HITES tenders [Hospitals Getting Upgraded Phase III; AIIMS Jhajjar; AIIMS Gorakhpur Bhatinda , Hospitals Getting Upgraded Phase-IV; this clause is mentioned that items should be from same company/ manufacturer.</p> <p>We are enclosing herewith recent tender pages of HSCC (India) Ltd. Tender No. HSCC/SES/MGMS/PGI/Neuro Science/2023 Date: 11.03.2023 for "Execution including Supply, Installation, Testing &amp; Commissioning of Medical Gas Manifold System (MGMS) for Advanced Neuro Science Centre at PGIMER, Chandigarh" where the mentioned items are from same principal company/manufacturer along with Manufacturer Authorisation [Copy Enclosed at Page 1 to 4].</p> <p>We therefore request to kindly incorporate that the mentioned Medical Gas Pipeline System items should be from same principal company/manufacturer along with Manufacturer Authorisation Letter.</p>	No change
Page 65, Para 9.1	<p>9. DISTRIBUTION PIPING  9.1 Copper pipe should be as per standard BS: EN 13348:2016/ ASTM B819 standards, Solid drawn, seamless, deoxidized, non-arsenical, half hard (hard can be accepted only for sizes 54mm or more), tempered and degreased copper pipe conforming to the standard. All copper pipes should be degreased &amp; delivered capped at both ends. The pipes should be accompanied with manufacturers test certificate for the physical properties &amp; chemical</p>	<p>We request the Medical Grade Copper Pipe should be BSI Kite Mark and CE Compliance Copper Pipes. Here, Lloyd is 3rd party Inspection Agency whereas Kite Mark product and service quality certification mark is owned and operated by the British Standards (BSI Group).</p> <p>It is a voluntary mark of manufacturers and service industries to demonstrate safety and reliability. The product has been proven to meet the agreed high standard.</p> <p>We therefore request Copper Pipe should be BSI Kite Mark and CE Compliance.</p>	No change

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
	composition.		
Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRMS	SUGGESTIONS BY HITES
Page 85, Para p	<p>Regarding Outlets of the Anesthesia &amp; surgeon Pendants, bidders have to supply same type of outlets as installed in the same building/block. Before shipment of the Pendants, bidders should take necessary action for selecting the same standard outlets and outlets should be BIS/European CE with 4 digit notified body number/USFDA approved</p>	<p>Before shipment of the Pendants, bidders should take necessary action for selecting the same standard outlets and outlets should be BIS / European CE with 4 digit notified body number/USFDA approved / UL / ETL Listed</p> <p>Remarks: Outlets installed in the pendants are not USFDA Certified but UL / ETL Listed. Please correct the same.</p>	No change
Page 86,87 Para 1 & 2	<p>WALL PANELING SYSTEM SMS Panel: Solid Mineral Composite Sheet (SMS) thickness of 03mm with thickness of panel including Aluminum backing structural panel (minimum 15mm thickness Al) consisting of a trapezoidal/Honeycomb aluminium corrugated core glued between two flat of aluminium sheet and total panel thickness not less than 18mm (3mm SMS +15mm Aluminium back) with suitable substructure frame. SMS panel should be bacteriostatic, dense &amp; non-porous material and unflamable (Reaction to fire class 1 norm)</p> <p>2 CEILING PANELING SYSTEM 2.1 SMS Panel: Solid Mineral Composite Sheet (SMS) thickness of 03mm with thickness of panel including Aluminum backing structural panel (minimum 15mm thickness Al) consisting of a trapezoidal/Honeycomb aluminium corrugated core glued between two</p>	<p>We request the total thickness of panel including Aluminium backing should be 6 mm instead of 15 mm. The 9 mm extra thickness will become bulky and will cover more space comparing to 6 mm thickness of aluminium panel and if the total thickness of panel will be 15 mm aluminium + 03 mm SMS thickness = 18 mm; the structure will become heavy and stability of ceiling panel will become week. Why should we take risk??</p> <p>The thickness does not make any difference, as quality of SMS is premium. We are also enclosing specifications for your kind reference of HLL Infra Tech Service Ltd. Tender Reference HITES/PCD/NCI-AIIMS/17-18 for NCI AIIMS Jhajjar at page no. 5 to 7. We therefore request the total thickness should be 09 mm [06 mm Aluminium backing+3 mm SMS].</p>	No change

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
	flat of aluminium sheet and total panel thickness not less than 18mm (3mm SMS +15mm Aluminium back) with suitable supports/substructure frame . SMS panel should be bacteriostatic, dense & non-porous material and unflamable (Reaction to fire class 1 norm)		
Page 86,87 Para 1 & 2	WALL PANELING SYSTEM CEILING PANELING SYSTEM	It should be European CE 4 digit notified body CE No. / UL Listed. Copy of the Certificate must be submitted along with the technical bid of tender  Remarks: The Wall and Ceiling Panel must have European CE Marked with 4 digit notified body CE No. / UL Listed with the substructure and other accessories complete to be provided by the same manufacturer.	No change
Page 88, Para 4.9	Return air exhaust cabinet should be made from SS304	We request Return air exhaust cabinet should be made from SS304/Aluminium. Aluminium is light weight material done with powder coated which is long lasting, rust free and durable.	No change
Page 88, Para 4.10	The control/ signal cabling from respective dedicated AHUs to respective MOTs' control panel & associated sensors, DDC Panels etc shall be provided by the MOT vendor for controlling temperature & RH inside the MOT.	As the AHU is in the scope of AHU vendor, we request we cannot control the AHU. We can only On/Off in the control panel. Temperature up/down, Humidity control, its configuration can only be controlled/done by HVAC vendor and not MOT Vendor. This is requested so that the load should not come on MOT control panel. AHU is controlled by BMS system, it is requested, option of additional controller should be provided. This responsibility should be de-scoped from MOT vendor.	No change
Page 93, Para 14	PENDANTS FOR ANESTHETIST AND SURGEON	Like other items we also request Pendants should also have "Import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for the product and copy of valid license should be submitted".	No change
Page 94, Para 14	Single arm moveable Pendant for Anesthetist c. Weight carrying capacity of the arm should not be less than 180 Kg. should have electromagnetic/pneumatic brakes. Double arm moveable Pendant for Surgeon c. Weight carrying capacity of the arm should not be less than 180 Kg. should	Should have electromagnetic brakes.  Remarks: Keeping Pneumatic brakes in the tender is an unnecessary burden as the user will be required to put a separate compressor pipeline for pneumatic brakes. Hence, we request you to kindly delete "Pneumatic Brakes" from the tender	No change

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
	have electromagnetic/pneumatic brakes.		
Page 94, Para 14	Anaesthetist pendant should have NIST connection for all gases to connect the MGPS system	<p>Pendant should have NIST connection and Manometer for all gases to connect the MGPS System</p> <p>Remarks: For Safety point, all the pendants must be provided with a NIST Connection and Manometer, to avoid any false information being given by the supplier</p>	No change
Page 95, Para 14	Surgeon pendant should have NIST connection for all gases to connect the MGPS system.	<p>Pendant should have NIST connection and Manometer for all gases to connect the MGPS System</p> <p>Remarks: For Safety point, all the pendants must be provided with a NIST Connection and Manometer, to avoid any false information being given by the supplier</p>	No change
Page 99, Para 22.p	<p>OT LIGHT WITH CAMERA</p> <p>Surgical Light System Should be BIS/ European CE with 4 digit notified body/US FDA certified or Declaration of Conformity for quoted model with ISO 13485 issued by notified body (European CE/CDSCO/NABCB).</p>	<p>Kindly amend as under in clear terms: "Surgical Light System should be BIS OR European CE with 4 digit notified body OR US FDA certified OR Declaration of Conformity for quoted model with ISO 13485 issued by notified body (European CE/CDSCO/NABCB)".</p>	No change (vendor has requested the same existing spec)
Page 99, Para 22.	HD LED FLAT PANEL MONITOR	<p>Request for addition of Technical Specification of Medical Grade 4k LED Flat Panel Monitor:</p> <p>a) Should be 30"-32" High Definition Progressive Scan Flatpanel</p> <p>Medical Grade Monitors with ceiling mounted spring arm suspension to support high definition / HDTV progressive Scan images and should be able to support and display DVI/HDTV, RGBHV, SVideo, Composite video signals. Aspect ratio 16:9/16:10. Resolution – 3840 X 2160 or better.</p> <p>b) The flat Panel suspension should be ready with the cables for integration of High Definition Digital (DVI / HDTV), RGBHV (High Resolution), SVHS (SVideo), Composite video signals to travel from the various sources of video like endoscopic camera, room camera, in light camera, high definition flat panel monitors, while assuring native resolution / signal.</p> <p>c) Monitor should capable of displaying from other sources like endoscope, microscope etc. necessary provision should be provided as standard.</p> <p>d) It should be Medical Grade Class-1 Device and European CE Declaration of Conformity to</p>	No change



Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
		<p>be provided.</p> <ul style="list-style-type: none"> <li>-HD Flat Panel Monitor should be done according to IP 54 regulations.</li> <li>-ESG Safety Glass Cover is must to protect the Monitor Screen from breakage and for additional Safety of Patient.</li> <li>-For optimizing the quality of Pictures, it should have Dicom Preset, BT 709, BT 1886 features.</li> <li>-Video Connectors on the back side of Monitor is to be hide by Cover of Aluminum from the Back side of Monitor.</li> <li>-Monitor should be integrated by Command Bar shown in the front side of Monitor.</li> </ul> <p>It should be USFDA/European CE certified.</p> <p>Remarks: The technical specification of Recording System included in the tender is not Medical Grade, the technical specifications belong to a very basic recording system with monitor.</p> <p>Since, the hospital is looking for upgraded Modular Operation Theatre, we request you to kindly incorporate the technical specifications of Medical Grade Recording System of AIIMS, Nagpur tender published by HSCC as stated in the left column. (Tender Copy attached)</p>	
Page 99, Para 22	Recording system	<p>Request for addition of Technical Specification of Medical Grade Recording System:</p> <ul style="list-style-type: none"> <li>a) Recording system to be offered separately (Only for non-integrated OTs).</li> <li>b) Recording system should be full HD medical grade monitor LCD 19"touch screen or more and having the one TB storage space and 1 SSD in addition for operating system.</li> <li>c) Data cable for communication from both pendants and monitors should be laid down upto outside of OT in a patch port for future expansion for all OTs where there is no integration</li> <li>d) Patch panel for power &amp; signal to be laid down for 31"-32" LCD Monitor at wall of MOT</li> <li>e) Recorder should be capable of recording video from other sources like microscopes, endoscopes etc. suitable provision should be provided as standard.</li> <li>f) Should be flushed mounted on the OT wall with suitable frame</li> <li>g) Recording system should be integrated streaming with streaming.</li> <li>h) ESG Safety Glass Cover is must to protect the Monitor Screen from breakage and for Additional Safety of Patient.</li> <li>i) Recording system should be done according</li> </ul>	No change

Tender Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE PROSPECTIVE BIDDERS	COMMITTEE RECOMMENDATIONS
		<p>to IP 54 regulations.  j) Recording System should have P-CAP Multi-Touch Display  k) It should be Medical Grade Class-1 Device and European CE Declaration of Conformity to be provided /USFDA</p> <p>Remarks: The technical specification of Recording System included in the tender is not Medical Grade, the technical specifications belong to a very basic recording system with monitor.  Since, the hospital is looking for upgraded Modular Operation Theatre, we request you to kindly incorporate the technical specifications of Medical Grade Recording System of AIIMS, Nagpur tender published by HSCC as stated in the left column. (Tender Copy attached)</p>	
Page 100, Para 23	23 Extra Works (Price should be Quoted Separately)	<p>Extra work prices should not be considered in the total price and should not be covered for L1 ranking</p> <p>Remarks: Extra item unit rates must not be covered under total price as bidders may take undue advantage and quote lesser price to get the work as the work of extra item is not mandatorily covered under the said tender contract</p>	No change