

Tender Notice No.: **GSIDC/ENGG/NIT-101/2019-2020 DATED 06/12/2019**

Last date of submission of pre-bid queries: 17th December, 2019

COMMON SET OF DEVIATIONS

SR. NO.	VOLUME NO.	CHAPTER / CLAUSE NO. / ITEM NO.	PAGE NO.	CLARIFICATION SOUGHT BY BIDDERS	DECISION OF GSIDC
1.	III	Item no. 1.2, 1.3, 1.5, 2.2, 2.3, 5.3, 5.4 & 10.1	-	Request to have 4-digit CE Compliance Certificate of class 1, under Medical Council Directives 93/42/EEC. Copy of CE Certificate must be attached in the tender	CE certificate is not mandatory.
2.	III	Item no. 1.6, 2.5, 3.4 & 5.5	-	Request to have European CE Marked with 4 digit notified body no./UL Listed.	Must comply with European CE marked 4 digit notified body. Copy of CE Certificate must be attached in the tender.
3.	III	Item no. 3.1	-	Requested to have Medical Compressor Air Plant capacity of 56cfm, with flow rate 1550 ltrs/min (+/-5%) acceptable	Medical Compressor Air Plant must comply Strictly to the details/specifications mentioned against the said items. (+/-5% acceptable).
4.	III	Item no. 3.3	-	Gas Outlets DISS Points front loading Surgical air 7 bar to be considered.	As per tender specifications.
5.	III	Item no. 7	-	Requested for clarification i.e. Indigenous or imported to be used. Requested to delete CE certification of European Standard from tender	Imported to be used and must comply with 4-digit European CE compliance certificate of class 1, under Medical Council Directives 93/42/EEC. Copy of CE certificate must be attached in the tender.

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6.	II	Chapter no. 2	20 -21	Requested to add below makes under list of approved makes:	
				1. 4 Stage Filtration for Medical Air Plant- Summit Hygronics	1. Make Summit Hygronics is acceptable provided product specifications are as per tender.
				2. Air H.P. Tubing- Technologie Medicale	2. Make Technologie Medicale is acceptable provided product specifications are as per tender and complying with H.T.M2022, C-11 and European CE Certification of European Standard.
				3. Filter for Vacuum Plant- - Summit Hygronics	3. Make Summit Hygronics is acceptable provided product specifications are as per tender.
7.	III	Item no. 3.1	-	Requested for clarification on whether on whether Medical Air plant is Simplex or Duplex or Triplex to be considered.	Medical air plant must be triplex type.
8.	Volume II	Chapter no. 2	19 - 22	Requested to add " GCE Group Europe " also as an approved make for item no. 1.1, 1.4, 1.6, 2.1, 2.4, 2.5, 3.2, 3.4, 5.2, 5.5, 7, 9.1, 9.2, 9.3 and 9.4.	Make GCE Group Europe is acceptable provided product specifications are as per tender and complying with H.T.M2022, C-11 and European CE Certification of European Standard.

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9.	Volume II	Chapter no. 2	19-22	Request to add “ Nikhil Medico Gases ” also as an approved make for item no. 1.2, 1.3, 1.5, 2.2, 2.3, 10 and 11.	Make Nikhil Medico Gases is acceptable provided product specifications are as per tender.
10.	Volume II	Chapter no. 2	20	Requested to add “ Air Receiver-Nikhil Medico Gases, Air Dryer-Trident, Accessories-Nikhil Medico Gases ” also as an approved make for item no. 3.1.	Make Nikhil Medico Gases is acceptable provided product specifications are as per tender.
11.	Volume II	Chapter no. 2	20	Requested to add “ GCE Group Europe/Schönn Medizin Technik Germany/Aktiv ” also as an approved make for item no. 3.3	Makes GCE Group Europe, Schonn Medizin Technik Germany and Aktiv are acceptable provided product specifications are as per tender and complying with H.T.M2022, C-11 and European CE Certification of European Standard.
12.	Volume II	Chapter no. 2	20 - 21	Requested to add “ Schönn Medizin Technik Germany/Aktiv ” also as an approved make for item no. 4.1, 4.2, 4.3 and 4.4.	Makes Schonn Medizin Technik Germany and Aktiv are acceptable provided product specifications are as per tender and complying with H.T.M2022, C-11 and European CE Certification of European Standard.
13.	Volume II	Chapter no. 2	21	Requested to add “ Vacuum Reservoir Tank-Nikhil Medico Gases ” also as an approved make for item 5.1.	Make Nikhil Medico Gases is acceptable provided product specifications are as per tender.

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14.	Volume II	Chapter no. 2	21	Requested to add " Azad " also as an approved make for item 5.3 and 5.4	Make Azad is acceptable provided product specifications are as per tender.
15.	Volume II	Chapter no. 2	21	Requested to add " Lloyds certified- Mandev Tubes " also as an approved make for item no. 6.	Make Mandev Tubes is acceptable provided product specifications are as per tender.
16.	Volume II	Chapter no. 2	22	Requested to add " GCE Group Europe/Nikhil Medico Gases " also as an approved make for item no. 8.	Makes GCE Group Europe and Nikhil Medico Gases are acceptable provided product specifications are as per tender and complying with H.T.M2022, C-11 and European CE Certification of European Standard.
17.	Volume III	Item no. 6		For copper pipes both Kite mark and Lloyd certification is asked. These two standards are different, the generally applicable standard for third party inspection is Lloyd thus only the same should be asked. Kite mark on other hand can be provided only be single supplier in India thus would lock the tender and provide no chance for competitive bidding. Alternatively, the specifications can also be mentioned as Kite mark or Lloyd certified.	Third party Lloyd Certification or Kite mark is must.

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18.	-	General	-	Requested to mention requirement of CE certification as an option for all the imported items which are currently asked only as per USFDA or UL or ETL listed.	Imported items should have CE certification of European standard or USFDA or UL or ETL listed.
19.	-	General	-	For all the imported items CE certificate from notified body number should be asked.	Imported item to have 4-digit European CE Compliance Certificate of class 1, under Medical Council Directives 93/42/EEC. Copy of CE Certificate must be attached in the tender
20.		General	-	For manifold systems ISO 10524-2: 2018 is asked which is applicable for only regulators and not entire manifold system. Thus, a general standard for Medical devices i.e. ISO 13485 should be asked.	Manifold should comply with ISO 13485 standard of Medical Devices.

Sr. No.	Volume No.	Item no.	Current description	May be read as
1.	Volume III	1.2	Supply, Installation, Testing and Commissioning of 2 X 10 Size of oxygen manifold complete with middle frame with chain for individual cylinder. Pig tail pipes & non return valves will be supplied with the manifold.(cylinder will be provided by the hospital) - It should be CE Certification of European Standard compliance and ISO 10524-2:2018.	Supply, Installation, Testing and Commissioning of 2 X 10 Size of oxygen manifold complete with middle frame with chain for individual cylinder. Pig tail pipes & non return valves will be supplied with the manifold.(cylinder will be provided by the hospital) - It should be either ISO 10524-2:2018/ ISO 10524-1:2018/ ISO 13485:2016 or CE Certification of European Standard compliance.
2.	Volume III	1.3	Supply, Installation, Testing, Commissioning of 4 cylinder emergency Oxygen manifold with middle frame with chain for individual cylinder, regulator, pig tail pipes & non return valves. It should be CE Certification of European Standard and ISO 10524-2:2018. Note: Cylinder will be provided by the hospital.	Supply, Installation, Testing and commissioning of 4 cylinder emergency Oxygen manifold with middle frame with chain for individual cylinder, regulator, pig tail pipes & non return valves. It should be either ISO 10524-2:2018/ ISO 10524-1:2018/ ISO 13485:2016 or CE Certification of European Standard compliance. It should be ISO 10524-2:2018 or CE Certification of European Standard. Note: Cylinder will be provided by the hospital.
3.	Volume III	1.5	Supply, installation, testing and commissioning of BPC Oxygen flow meter with Humidifier Bottle 0-15 L/min standard flow rate. It should be CE Certification of European Standard and ISO 9001-2008.	Supply, installation, testing and commissioning of BPC Oxygen flow meter with Humidifier Bottle 0-15 L/min standard flow rate. It should be ISO 9001-2008 or CE Certification of European Standard.

Sr. No.	Volume No.	Item no.	Current description	May be read as
4.	Volume III	2.2	Supply, installation, testing and commissioning of 2 x 2 Size of Nitrous Oxide manifold complete with middle frame with chain for individual cylinder. Pig tail pipes & non return valves will be supplied with the manifold. It should be CE Certification of European Standard and ISO 10524-2:2018. Note: Cylinder will be provided by the hospital.	Supply, installation, testing and commissioning of 2 x 2 Size of Nitrous Oxide manifold complete with middle frame with chain for individual cylinder. Pig tail pipes & non return valves will be supplied with the manifold. It should be either ISO 10524-2:2018/ ISO 10524-1:2018/ ISO 13485:2016 or CE Certification of European Standard compliance. Note: Cylinder will be provided by the hospital.
5.	Volume III	2.3	Supply, installation, testing and commissioning of 2-cylinder emergency Nitrous Oxide manifold with middle frame with chain for individual cylinder, regulator, pig tail pipes & non return valves. It should be CE Certification of European Standard and ISO 10524-2:2018. Note: Cylinder will be provided by the hospital.	Supply, installation, testing and commissioning of 2-cylinder emergency Nitrous Oxide manifold with middle frame with chain for individual cylinder, regulator, pig tail pipes & non return valves. It should be either ISO 10524-2:2018/ ISO 10524-1:2018/ ISO 13485:2016 or CE Certification of European Standard compliance. Note: Cylinder will be provided by the hospital.
6.	Volume III	2.5	Supply, Installation, Testing, Commissioning of N2O H.P. Rubber tube of lue color. It should be CE Certification of European Standard.	Supply, Installation, Testing, Commissioning of N2O H.P. Rubber tube of blue color. It should be CE Certification of European Standard.
7.	Volume III	5.3	Supply, installation, testing and commissioning of Ward Vacuum Unit with one Vacuum Regulator & one 2000 ml collection jar. It should be CE Certification of European Standard.	Supply, installation, testing and commissioning of Ward Vacuum Unit with one Vacuum Regulator & one 2000 ml collection jar.

Sr. No.	Volume No.	Item no.	Current description	May be read as
8.	Volume III	5.4	<p>Supply, installation, testing and commissioning of Operation Theatre vacuum unit trolley mounted complete with 1 no. of high suction regulator along with twin vacuum collection jar of Polysulphone of 2000 ml with lid.</p> <p>It should be CE Certification of European Standard.</p>	<p>Supply, installation, testing and commissioning of Operation Theatre vacuum unit trolley mounted complete with 1 no. of high suction regulator along with twin vacuum collection jar of Polysulphone of 2000 ml with lid.</p>
9.	Volume III	10.1	<p>Supply, Installation, Testing, commissioning of 1500 MM HORIZONTAL/VERTICAL BED HEAD PANEL - Double Duct. It should be CE Certification of European Standard. It should be constructed of extruded aluminium profiles with 2 channels to provide a modular surface mounted unit with integrated accessory rails for equipment management.</p> <p>It should have 2 separate partition rows wise for medical gases and electrical Switch & sockets.</p> <p>Length should be 1500mm.</p> <p>All medical gas piping shall be hard-piped and brazed to a single point of connection.</p> <p>Fascia panels, top, middle and bottom cover panels shall be removable for access for easy installation and maintenance.</p> <p>It should be pre piped with provision for 6 - 8 gas outlets. (Bed head panels does not include gas outlet cost) It should have 6 electrical sockets, 1 number RJ-45, and 1 number RJ-11). It should have one stainless steel vertical pole with IV stand and 4 hooks on which dedicated accessories can</p>	<p>Supply, Installation, Testing, commissioning of 1500 MM HORIZONTAL/VERTICAL BED HEAD PANEL - Double Duct. It should be constructed of extruded aluminium profiles with 2 channels to provide a modular surface mounted unit with integrated accessory rails for equipment management.</p> <p>It should have 2 separate partition rows wise for medical gases and electrical Switch & sockets.</p> <p>Length should be 1500mm.</p> <p>All medical gas piping shall be hard-piped and brazed to a single point of connection.</p> <p>Fascia panels, top, middle and bottom cover panels shall be removable for access for easy installation and maintenance.</p> <p>It should be pre piped with provision for 6 - 8 gas outlets. (Bed head panels does not include gas outlet cost) It should have 6 electrical sockets, 1 number RJ-45, and 1 number RJ-11). It should have one stainless steel vertical pole with IV stand and 4 hooks on which dedicated</p>

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			<p>be mount. Out of two partitions one partitions should have medical gas piping. It shall be hard-piped and brazed to a single point of connection. Fascia panels, top, bottom cover panels shall be removable for access for easy installation and maintenance. Design to meet the need of the dental wards. Designed to make dental recovery more pleasant, should be made of an innovative polycarbonate sheet onto which it is applied a colorful film, featuring pictures recomanded by user.</p>	<p>accessories can be mount. Out of two partitions one partitions should have medical gas piping. It shall be hard-piped and brazed to a single point of connection. Fascia panels, top, bottom cover panels shall be removable for access for easy installation and maintenance. Design to meet the need of the dental wards. Designed to make dental recovery more pleasant, should be made of an innovative polycarbonate sheet onto which it is applied a colorful film, featuring pictures recommended by user.</p>