Technical Specification for Operation Theatre Light, LED

S.N.	Purchaser's specification	Bidder's offer
	Operation Theatre Light, LED	
	Manufacturer	
	Brand	
	Type / Model	
	Country of Origin	
1	**Description of Function**	
1.1	Surgical lights illuminate the surgical site for optimal visualization of small, low-contrast objects at varying depths in incisions and body cavities.	
2	**Operational Requirements**	
2.1	It shall be latest LED technology shadowless operating light field with 2 units, one major dome and one satellite dome.	
3	**System Configuration**	
3.1	Operation Theatre Light, LED with all standard accessories.	
4	**Technical Specifications**	
4.1	Shall be ceiling mounted LED Operation Theatre light with microprocessor-based technology.	
4.2	Shall have single colour high performance LEDs with lifetime more than 40,000 hours of operation.	
4.3	It shall have dual dome with main light and satellite light.	
4.4	Lux intensity: minimum 140,000 Lux for major dome and minimum 100,000 Lux for satellite dome.	
4.5	Shall be minimum 20 cm light field diameter	
4.6	Colour temperature shall be between 4000 to 4500 degree K.	
4.7	Colour rendering index minimum 90	
4.8	Depth of illumination shall not be less than 100 cm.	
4.9	Illumination adjustment 25%(±5) to 100%.	
4.10	Height adjustment more than 1 metre.	
4.11	Light field adjustment	
4.12	Shall have stable illumination throughout the life period of the light.	
4.13	Shall have light focusing adjustment fixed on the dome or arms.	
4.14	The intensity of light shall be uniform during the surgery.	
4.15	Total 70 or more LEDs in combination of two domes	
5	**Accessories, spares and consumables**	
5.1	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).	
	Sterilizable handle : 2 nos. for each dome	
6	**Operating Environment**	
6.1	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.	
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.	
7	**Standards and Safety Requirements**	
7.1	Submit product's valid ISO 13485 for medical device	
7.2	Submit product's valid EUCE certificate **or** official extension notice issued directly by the notified body, clearly listing the offered model **or** MDR (EU) 2017/745 for offered medical device **or** USFDA approved product	
8	**User Training**	

S.N.	Purchaser's specification	Bidder's offer
8.1	Must provide user training (including how to use and maintain the equipment).	
9	**Warranty**	
9.1	Comprehensive warranty for 2 years after acceptance.	
9.2	Submit commitment letter from the manufacturer for availability of spare parts for 5 years after completion of warranty period	
10	**Maintenance Service During Warranty Period**	
10.1	During the warranty period supplier must ensure corrective/breakdown maintenance whenever required.	
11	**Installation and Commissioning**	
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.	
12	**Documentation**	
12.1	User (Operating) manual in English.	
12.2	Service (Technical / Maintenance) manual in English.	