Semi-Automated Bio-Chemistry Analyser

S.N.	Purchaser's Specifications	Bidder's Offer
	Semi-Automated Bio-Chemistry Analyser	
	Manufacturer	
	Brand	
	Type / Model	
	Country of Origin	
1	**Description of Function**	
1.1	The Semi-automated Bio-chemistry Analyser measures biochemical indices by analyzing blood and other body fluids, then combines with other clinical information, to help diagnose disease, evaluate organ function.	
2	**Operational Requirements**	
2.1	Semi-automated Chemistry Analyser with built in thermal printer.	
2.2	User programmable memory for up to 150 test and minimum 1,000 sample test results.	
3	**System Configuration**	
3.1	Semi-automated chemistry Analyser with inbuilt thermal printer data processor & LCD display	
4	**Technical Specifications**	
4.1	Light Source: Quartz Halogen or LED lamp	
4.2	Photo detector: Silicon based or equivalent	
4.3	Wavelength Range: Approx. 340 – 700 nm.	
4.4	Wavelength Selection: Automatic	
4.5	Photometric Range: Approx. 0 to 3.0 Absorbance or above	
4.6	Calculation Modes: Should have at least 5 calculation modes like • Absorbance • concentration • End point • Two points • Kinetic	
4.7	• Incubation Time 1 to 300 seconds. • Interval Time 1 to 300 seconds.	
4.8	Quality Control facility. Must supply two level QC.	
4.9	Calibration method- should have facility of calibration of at least factor, calibrator, multipoint calibration.	
4.10	Flow Cell- Temperature control is required.	
4.11	Incubator- Incubator block with 37 degree Celsius	
5	**Accessories, spares and consumables**	
5.1	**Accessories:** • Test kits for at least 10 various parameters, calibrators/standard and controls.	
5.2	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).	
6	**Operating Environment**	
6.1	The system offered shall be designed to operate normally under the conditions of the purchaser's country. The conditions include Power	

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	Supply, Climate, Temperature, Humidity, Altitude, etc.	
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug.	
7	**Standards and Safety Requirements**	
7.1	Must submit ISO 13485:2016 for Medical Devices **AND**	
7.2	The bidder shall submit a valid CE certificate demonstrating compliance with the In Vitro Diagnostic Regulation (IVDR) 2017/746 (or previously under In Vitro Diagnostic Medical Devices Directive (IVDD) 98/79/EC) or USFDA approved product certificate. Self-declaration of CE conformity shall not be accepted	
7.3	Shall meet IEC 61010-2-081safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.	
8	**User Training**	
8.1	Must provide user training (including how to use and maintain the equipment) at onsite at the time of installation.	
9	**Warranty**	
9.1	Comprehensive warranty for 2 years from acceptance.	
10	**Maintenance Service During Warranty Period**	
10.1	During the warranty period supplier must ensure planned preventive maintenance (PPM) and 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	
12.3	Certificate of calibration and inspection as per manufacturer guideline.	
12.4	Manufacturer shall provide commitment letter for availability of spare parts for 5 years after warranty period.	