Fully Automated Haematology Analyser (3 Parts Differential)

S.N.	Purchaser's Specifications	Bidder's Offer
	Fully Automated Haematology Analyser (3 Parts Differential)	
	Manufacturer	
	Brand	
	Type / Model	
	Country of Origin	
1	**Description of Function**	
1.1	Automated haematology analyser or complete blood cell counter is used to count various types of blood cells in the blood.	
2	**Operational Requirements**	
2.1	Fully automated 3 parts differential haematology analyser.	
3	**System Configuration**	
3.1	Fully Automated Haematology Analyser, complete unit with all standard reagents, consumables and accessories.	
4	**Technical Specifications**	
4.1	Determination of minimum 18 parameters, with 3-part differential, for routine haematology.	
4.2	Shall have fully automatic	
4.3	Throughput: minimum 50 samples per hour.	
4.4	Determination of: Red blood cell(RBC), White blood cell(WBC), Haemoglobin(HGB), Haematocrit(HCT), Mean cell volume(MCV), Mean cell haemoglobin(MCH), MCHC, Red cell distribution(RDW-SD and RDW-CV), Platelets(PLT),Platelet distribution(PDW-SD and PDW-CV), Mean platelet volume(MPV), differential leucocytes (LYM, LYM%, MID, MID%, GRA, GRA%),	
4.5	Method: Photometry and impedance technology, cyanide-free colorimetry for haemoglobin counting.	
4.6	Calibration: independent automated calibration and manual calibration for minimum two test modes.	
4.7	Shall have with self-test capability.	
4.8	Display: LCD screen.	
4.9	Indication of self-test failures and assistance messages, sample ID, date and time are reported with test results.	
4.10	Supplied complete with dedicated data analysis and data management software.	
4.11	Shall have built-in RS232, USB2.0 or equivalent, for allowing data transfer and network capability via LIS.	
4.12	On board memory for at least 150 tests records.	
4.13	Shall quote rates for reagents & consumables, calibrators & controls, printer paper, separately and it must be valid for at least 3 years.	
5	**Accessories, spares and consumables**	
5.1	Reagents & consumables & controls to be supplied for 100 samples.	
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 product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The	

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	conditions include Power Supply, Climate, Temperature, Humidity, Altitude, etc.	
6.2	Power supply: 220-240VAC, 50Hz fitted with appropriate plug	
6.3	Suitable pure sine wave online UPS with maintenance free batteries, voltage regulation and spike protection for minimum 30 min.	
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 61010-2-081 safety 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 after acceptance.	
10	**Maintenance Service During Warranty Period**	
10.1	During the warranty period supplier must ensure preventive maintenance 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.	