TECHNICAL SPECIFICATIONS OF MEDICAL EQUIPMENT FOR BLOCK PUBLIC HEALTH LABORATORY(BPHL)

HEALTHCARE TECHNOLOGY DIVISION

NATIONAL HEALTH SYSTEMS RESOURCE CENTRE

Table of Contents:

PORTABLE HANDHELD GLUCOMETER		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Glucose self-testing
GMDN code(s)		CT296
GENERAL		
1. USE		
1.1	**Clinical purpose**	It intended to be used together for testing, either at the point-of-care or in self-testing by a layperson, for the quantitative measurement of glucose and/or ketones in a whole blood clinical specimen.
1.2	**Clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Should be open system having compatibility with any make of available glucose strips in open market. 2. Should have LCD display screen and auto shut off feature when not in use. 3. Display of the sugar reading should be in mg/dl. 4. Should have reading range/linearity from 20 to 700 mg/dl. 5. Should have a maximum reading time of less than 10 seconds 3. Should be supplied with autoinjector pen and disposable lancets. 4 Should have the feature of automatic code detection of glucose strips. 5. Should have a minimum memory of 100 tests
2.2	**User's interface**	LCD
2.3	**Software and/or standard of communication**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Handheld Device
3.2	**Weight (lbs, kg)**	Handheld Device
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Handheld Device
4. ENERGY SOURCE		
4.1	**Power Requirements**	Battery powered
4.2	**Battery operated**	3-volt lithium coin cell battery or 2 x (AAA) Alkaline Batteries
4.3	**Protection**	NA

4.4	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	Glucose strips (able to use capillary blood samples) with availability in local market
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	User training should be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	01 Years
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals should be supplied along with machine diagrams
10.2	**Other accompanying Documents**	NA
	11. NOTES	
11.1	**Other information**	Contact details of manufacturer and supplier should be provided.
11.2	**Recommendations or Warnings**	NA

SEMI-AUTOMATED BIOCHEMISTRY ANALYSER		
Version no.:		02
Date:		August 2023
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Multichannel clinical chemistry analyser IVD, laboratory
GMDN code		56677
GENERAL		
1. USE		
1.1	**Clinical purpose**	A semi-automated laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of multiple clinical chemistry analytes in a clinical specimen. Analytes detected may include electrolytes, specific proteins, lipids and kidney, liver and cardiac function test analytes.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Analyzer should have ability to use external cuvettes and integrated flow cell. • Analyzer should have more than 200 programmable channels. • Open Ended system preferably. • Analyzer should have 5 assay types: End point, Fixed time, Kinetic, absorbance and 1-point calibration with option for extended keyboard. • Analyzer should have calibration types: Linear factor, multi-point, point to point and Log-Log out • Facility for kinetic assay measurement with multiple standard mode. • Should have minimum 10,000 Patient Result memory Storage. • Should have light source with working life of more than 10000 hrs. • Should have complete visual range. • 3 levels control with day-to-day Levey Jennings chart stored and displayed. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility
2.2	**User's interface**	• Facility for integration with PC • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/or standard of communication (wherever required)**	NA

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.6	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE		
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS system for backup of minimum one hour
4.4	**Protection**	NA
4.5	**Power consumption**	To be specified by manufacturer/supplier
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open,closed system)**	1. Light source/Lamp-1 no. 2. Micro pipettes (5 No.) - 2 variable (5-50), (100-1000) 3. Tips 500 - small and 500- big.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements:nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.

8.3	**Training of staff (medical,paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: - 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost.
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landlinenumber)**	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed

FULLY AUTOMATED BIOCHEMISTRY ANALYSER		
Version no.:		02
Date:		August 2023
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Multichannel clinical chemistry analyser IVD, laboratory
GMDN code		56677
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be used forthe qualitative and quantitative in vitro determination of multiple clinical chemistry analytes in a clinical specimen. Analytes detected may include electrolytes, specific proteins, lipids and kidney, liver and/or cardiac function test analytes.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The equipment should be capable of all RoutineSTAT and special Biochemical tests including specific protein, therapeutics, and user defined applications in clinical sample like whole blood, serum, plasma, urine and body fluids. 2. Throughput: minimum 200 tests/hour. 3. Measurement principle: photometric analysis. 4. Open Ended system preferably. 5. Optical System should have Wavelength range from340 to 700 nm. 6. Should have built in Cooled reagent Compartmentwith sample volume 2- 40 µl. 7. Auto diagnosis of machine errors with message and correction steps. 8. Must have on board capacity for permanent and numbered cuvettes. 9. Separate probe for reagents and sample. 10. Laundry System with minimum 5 step washing. 11. Minimum carryover of not more than 0.05 ppm. 12. Should have external and internal probe cleaning facility. 13. The system should be having the facility of both auto-calibration and manual. 14. Should have solid state light source (LED Technology) with a split reference beam with workinglife of more than 10000 hrs. 15. Should have minimum 50,000 Patient Result memory Storage

		16. Online QC Tracking with Levy and Jennings Chart for upto 30 different points, SD and CV. 17. Provision for Bar Code/QR code reading should be available. 18. The equipment should have in-built digital display unit and PC interface facility.
2.2	**User's interface**	• Digital display • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/or standard of communication (wherever required)**	Built - in/Automatic/compatible, window based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis.
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)	
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS system with minimum one hour back up
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables/reagents(open,closed system)**	1. Suitable Water plant/Purification System on RO or any latesttechnology. 2. External printer. 3. UPS online pure sine wave for back up of system withPC and IT peripherals for one hour. 4. One light source.
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (airconditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.

6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performanceand safety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operationchecks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits at least one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: - 1) User, technical and maintenance manuals to be supplied inEnglish/Hindi language along with machine diagrams. 2) List of equipment and procedures required for localcalibration and routine maintenance. 3) Certificate of calibration and inspection
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost.
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a tollfree/landline number)**	Contact details of manufacturer, supplier and local service agent tobe provided.
11.2	**Recommendations orwarnings**	Any warning signs should be adequately displayed

CHEMILUMINESCENT IMMUNOASSAY ANALYSER IVD		
Version no.:		01
Date:		August 2023
Done by: (Name/institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Chemiluminescent immunoassay analyzer IVD
GMDNS code(s)		56701
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be usedfor the qualitative and quantitative in vitro determination of chemical and biological markers (e.g., protein, drug, hormone, microbial toxin) in a clinical specimen.
1.2	**Used by clinical departme nt/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type ofdevice)**	• Fully Automated multi-channel analyzer based on chemiluminescence technology. • The instrument should provide comprehensive process check that performs, monitors, and verifies each step throughput sample and assay processing. • Continuous loading capacity of 30 or more samples. • Throughput of atleast 60 test per hour or more • The system should be able to read multiple barcode types or QR code. • It should have capability to do the assay in continuous, random, batch & stat mode. • Serum, plasma, urine, whole blood (assay-dependent) type of samples handling system. • System to use latest mixing probe technology to mix the samples and reagents to have complete uniformity with clot detection facility. • It should have the facility for bubble detection, check viscosity, sample level and short samples to ensure accuracy preventing erroneous results due to improper samples. • It should have an ability to do on board dilution andreflex dilution for high and abnormal samples. • It should have facility for automated probe cleaning or disposable tips system to avoid reagent carryover. • Should have onboard liquid waste container (4 litre), direct drain optional.

		• Should be a microprocessor-controlled device withdigital display. • 2-point re-calibration facility, switched mode power supply, automated instrument calibration, user friendly and intelligent software • System should have software that automatically generates LJ charts for QC and have appropriate alerts. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility. • External USB storage available
2.2	**User's interface**	• Digital display • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/ or standard of communication (Wherever required)**	Built - in/Automatic/compatible, windows based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	System should have on-board cooling facility to maintain the temperature of the reagents.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	Online UPS with minimum one hour back up
4.3	**Protection**	Internal electrical protection.
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	• External Printer to take printout of patient results andQC reports. • Online UPS with minimum one hour backup
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		

6.1	**Atmosphere/Ambience(air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterilityissues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre- market, sanitary,); Performance and safety standards (specific to the devicetype); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality,tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operationchecks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in eachquarter
10. DOCUMENTATION		
10.1	**Operating manuals,set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should besupplied in English/Hindi language along with machine diagrams. 2. Advanced maintenance tasks documentation. 3. Certificate of calibration and inspection, 4. Satisfactory certificate for any existing installationfrom government hospital.

10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and localservice agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

Haemoglobinometer		
Version no. :		01
Date:		August 2023
Done by : (Name, Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	Haemoglobinometer is intended to be used for quantitative measurement of haemoglobin in fresh capillary or whole blood samples.
1.2	**Used by clinical department/ward**	Clinical lab, POC device
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. It should be an automated, integrated system and based on Photometry. 2. Open system (preferably) with direct read-out on LED/LCD display for estimation of hemoglobin. 2. Should have LCD display screen and auto shut off feature when not in use. 3. Should display results in g/dl. 4. Measuring Range 0 to 25 g/dl 6. Should have automatic calibration system for maintaining accuracy of reading (<5%CV). 7. Should have rechargeable batteries (3.6 V). 8. Should have USB connectivity interface for PC and printer. 9. Should be supplied with autoinjector pen and disposable lancets.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required)**	NA

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise-free system
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE		
4.1	**Power requirements**	NA
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Hb Strips
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature -10 to 60 deg and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements:**	NA

	nature, values, quality, tolerance	
8.2	**Requirements for sign-off**	Supplier to perform safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	01 year
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. Certificate of calibration and inspection,
10.2	**Other accompanying documents**	NA
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer and supplier to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

HEMATOLOGY ANALYZER (3 PART)		
Version no.:		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Haematological cell analyser IVD
GMDN code(s)		35476
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be used for the enumeration of a haematological cell population, using technology to measure and calculate white cell, redcell and platelet parameters and indices in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The system should have end point, kinetic, fixed time and turbidimetric mode. • The system should be capable of 3-part WBC differential, estimating minimum 18 parameters with linearity (WBC, TC, RBC, Hb, hematocrit, MCV, MCH, MCHc, RDW- SD/RDW-CV, PLT, MPV, Pt Crit, PDW, PLCR optional). • The system should have memory of a minimum of 10000 patient samples. • The system should have high intensity LED sourcefor Hb estimation. • The system should have dual mode – flow cell and cuvette. Non-cyanide based is preferable. • External keyboard. • Automated standby and wake up. • Auto probe cleaning and sample dilution preferable. • System must have throughput of at least 60 samples per hour. • QC Mode: LJ, SD, CV, QC histogram • Provision for Bar Code/QR code reading should be available • Built-in voltage stabilizer and test results printing facility. • The equipment should have in-built digital display unit and PC interface facility
2.2	**User's interface**	• Touch screen (Coloured) • Provision for bi-directional LIS/HIS interface shouldbe available.

2.3	**Software and/or standard of communication (wherever required)**	To be provided by manufacturer
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	N/A
3.2	**Weight (lbs, kg)**	N/A
3.4	**Noise (in dBA)**	N/A
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and theheat should be disbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary laboratory Installation.
4. ENERGY SOURCE		
4.1	**Power Requirements**	220 +-10% VAC, 50 HZ
4.2	**Battery operated**	UPS system with minimum 1 hour back up
4.7	**Protection**	Internal electrical protection
4.8	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables/reagents(open, closed system)**	• 2D-Barcode/ QR code Scanner. • Built-in Thermal printer and provision for external printer. • All the consumables, controls and calibrators and any other reagents or items required for conducting 1000 tests should be mentioned and supplied with the equipment. • Online UPS for minimum 1 hour back up.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performanceand safety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		

8.1	**Pre-installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	• Supplier to perform installation, safety and operation checks before handover. • Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 3 years, including all spares and calibration. • Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, servicemanuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied inEnglish/Hindi language along with machine diagrams. 2) List of equipment and procedures required for localcalibration and routine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of essential spare/ accessories, reagents/all other consumables along with their part number and cost shouldbe quoted
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier, and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed;

Hematology Analyzer (5 PART)		
Version no. :		02
Date:		August 2023
Done By (Name/Institution		HCT/NHSRC
NAME AND CODING		
GMDN name		Haematological Cell Analyser IVD
GMDN code(s)		35476
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be used forthe enumeration of a haematological cell population, using technology to measure and calculate white cell, red cell and platelet parameters and indices in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Five-part differential with reticulocyte count based onthe principle of flow cytometry including minimum 24 parameters with two histograms and scattergrams for RBC and PLT: BASO, WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS%, BAS%, RBC, HCT,MCV, RDW-SD, RDW-CV, HGB, MCH, MCHC, PLT, PCT, MPV, PDW-SD, PDW-CV. • Advanced, integrated self-cleaning system. • Stores minimum 25,000 test results with histogramsand scattergrams. • Sample Material - EDTA blood with atleast pre-diluted mode and whole blood mode. • Integrates with common practice management systems including cleaning of apertures, tube systems and calibration. • Should be able to perform all parameters on variable sample volume for adult and pediatric patients. • Should be able to avoid micro-RBCs interference in platelet count. • System must have throughput of at least 60 or more samples per hour. • Should be equipped with automatic sample loading, mixing and testing. Also have manual mode andSTAT modes along with Random access for individual samples. • Open system • Pre-diluted mode and whole blood mode • QC Mode LJ, SD, CV, QC histogram. • Provision for bi-directional LIS interface should be available. • Provision for Bar Code/QR code reading should be

		available. • The equipment should have in-built digital display unit and PC interface facility.
2.2	**User's interface**	Touch screen and PC
2.3	**Software and/or standard and communication (wherever required)**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Should maintain nominal temperature and theheat should be disbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
	4. ENERGY SOURCE	
4.1	**Power Requirements**	220 +-10% VAC, 50 HZ
4.2	**Battery operated**	UPS System with minimum back up time of one hour.
4.6	**Protection**	N/A
4.7	**Power consumption**	As specified by the manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables/reagents(open,closed system)**	• 2D-Barcode/QR Code Scanner. • PC, Keyboard, Printer • Reagents: All the reagents required for 1000 tests should be supplied with the equipment along with one set of tri level control.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (airconditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performanceand safety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. TRAINING AND INSTALLATION	

8.1	**Pre-installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, servicemanuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied inEnglish/Hindi language along with machine diagrams. 2) List of equipment and procedures required for localcalibration and routine maintenance. 3) Service and operation manuals (original and copy) to beprovided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbersand cost;
11. NOTES		
11.1	**Service Support Contactdetails (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent tobe provided.
11.2	**Recommendation s orwarnings**	Any warning signs should be adequately displayed.

ERYTHROCYTE SEDIMENTATION RATE (ESR) ANALYSER		
Version no.:		01
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Erythrocyte Sedimentation rate (ESR) analyser IVD
GMDN Code		56691
GENERAL		
1. USE		
1.1	Clinical Purpose	An electrically powered automated laboratory instrument intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics (Specific to this type of device)	• The instrument should carry out automated ESR analysis directly from closed ESR tubes or EDTA vacutainers using the principle of sedimentation of red blood cells (Westergren Method). • Should be able to load minimum 10 samples at a time. Both batch and continuous. • Measuring range in mm: 1-140 using optical sensor. • Throughput should be at least 60 samples/hr. • ESR controls should have long shelf life (minimum 6 months). • Should have an inbuilt Bar code Reader and printer. • Should have auto mixing facility as per ICSH & CLSI requirements. • Have provision for internal temperature correction at 18°C or 37° C • Should have feature of haemocrit HCT correction. • Should offer random access testing. • Data storage capacity: upto 1000 test results. • Internal Quality Control Management with a minimum of two level of control should be provided. • Should have facility for calibration and should comply with National/International quality standards. • Provision for bi-directional LIS interface should be available. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility.

2.2	**User's Interface**	Microcontroller based LCD/LED Display Unit
2.3	**Software and/or standard of communication (Wherever required)**	All software installations or updates should be done free of cost during warranty period.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (in mm)**	NA
3.2	**Weight**	NA
3.3	**Noise**	NA
3.5	**Heat Dissipation**	NA
3.6	**Mobility/Portability**	Stationary Lab Installation
4. ENERGY SOURCE		
4.1	**Power input**	220VAC +/- 10%, 50 Hz.
4.2	**Battery Operated**	Yes
4.3	**Protection**	Internal Electrical Safety
4.2	**Power consumption**	As per Manufacturer/Supplier specified
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	**Accessories, (mandatory, Standard, operational);Spare parts (main ones) Consumable/reagents(Open, closed system)**	1. Reagents and consumables to carry out minimum 200 tests 2. One additional set of RS 232 cables 3. Other Standard accessories.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere /Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS & SAFETY		

7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the devicetype); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and duringPreventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	**1.** 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals,service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Certificate of calibration and inspection. 4. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of all the important spares and accessories, with their part numbers and cost needs to be submitted.
11. NOTES		

11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of Vendor and local service agent needs to be provided.
11.2	Recommendations or warnings	Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medical device needs to be mentioned.

COAGULATION ANALYZER		
Version no.:		01
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Coagulation analyzer IVD, laboratory
GMDNS code(s)		56689
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of one or multiple coagulation components involved in hemostasis in a clinical specimen (e.g., performs tests such as prothrombin time (PT), partial thromboplastin time (PTT))
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Blood Coagulation analyzer should be a fully automated (It should automatically aspirate, dispense, incubate and measure) with random access. • The system must be open for essential reagents. • Should have option for clotting, Chromogenic, turbidimetric, fluorogenic or immune assays as well. • Instrument should be able to detect automatically positive sample and reagent positions. • Possibility of auto rerun and auto redilution of samples should be available, positive sample andreagents level detection should be provided. • It should support a wide range of parameters including PT, APTT, Factor Assay, Protein C, Protein S, Fibrinogen, and Thrombin Time, ATIII,Heparin, PLG, LP(a), APCR, DDI, FDP, vWf. Factor VIII quantification. • Throughput: Must perform at least 20 tests (for APTT and PT) per hour. • Storage: It should have capacity of storing 1000test results in its memory. • System should have on-board cooling facility tomaintain the temperature of the reagents. • Machine should provide patient analysis curve. The instrument should have in-built Barcode

		reader for identification of sample and reagents i.e. name, stability, volume, position etc. • System should have software that automatically generates LJ charts for QC and have appropriate alerts. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility.
2.2	**User's interface**	• LCD Display • Provision for bi-directional LIS interface should be available.
2.3	**Software and/ or standard of communication (wherever required)**	In built – to be provided by the manufacturer
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS of suitable kVA with at least 1 hour backup.
4.3	**Protection**	Internal electrical protection.
4.4	**Power consumption**	To be specified by manufacturer/vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard,optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	1. All the consumables, controls and calibrators and anyother reagents or items required for conducting 500 tests should be mentioned and supplied with the equipment. 2. Barcode/QR code Scanner 3. Built-in Thermal printer or provision for external printer 4. Online UPS for minimum 1 hour back up
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience(air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		

7.1	**Certificates (pre- market, sanitary,); Performance and safety standards (specific to the device type); Local and/or International**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (Medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 3 years, including all spares and calibration. • Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals,set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) tobe provided. 3. Certificate of calibration and inspection, 4. Satisfactory certificate for any existing installationfrom government hospital.
10.2	**Other accompanying Documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and localservice agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

BINOCULAR MICROSCOPE		
Version no.:		02
Date:		August 2023
Done by: (name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		NA
GMDNS code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	A microscope is a laboratory instrument used to examine objects that are too small to be seen by the naked eye. Microscopic analysis of specimens helps diagnose diseases by looking at cellular morphology and presence of infectious agents and other microscopic structures. Binocular microscope is a microscope that lets the viewer use both eyes as it has 2 eye lenses.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Body-Single mold sturdy stand inclined Binocular body 30 °, 360º rotatable head without adjusting screws with inter-pupillary distance of 50-75mm. • It should have LED light source with rechargeable battery system. • Eyepieces-Paired high quality 10X/20mm wide angle anti fungus field eyepiece. one with pointer. Diopter adjustment must be present on both eye pieces. • Objectives-Parfocal, antifungal coated 4x, 10x, 40x and 100x having numerical aperture 0.1, 0.25, 0.60-0.65 and 1.25-1.65 respectively. Oil immersion objective (40x and 100x) should be spring loaded. All objectives should be plan achromatic, antifungal coated infinity and color corrected. Objective should be well centered even if their position on turret is changed. • Mechanical stag- ceramic coated surface with vernier scale on X-Y axis and slide holder. • Condenser, numerical aperture (NA) 1.25 focusable with rack and pinion arrangement incorporating spherical lens and iris diaphragm. It should have filter holder and swing in/out blue filter.

		• Should have inbuilt protective safety device which can withstand fluctuations of voltage from 140 V-280V. • LED illumination 3W with intensity control knob > 10,000 Hrs bulb lifespan with battery backup of 1 hrs and charging indication. • Focusing knob should have coaxial coarse and fine focusing knobs. Fine focusing movements should have sensitivity of 2 micron or less, coarse focus with torque adjustment, focusing stop for slide safety should be there.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer/vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	Should be provided with wooden storage box, dust cover, immersion oil.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances.

6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Advanced maintenance tasks documentation. 4. Certificate of calibration and inspection. 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.

11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

ELISA READER AND WASHER		
Version no.:		01
Date:		August 2023
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		-
GMDN code		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory technique that uses antibodies linked to enzymes to detect and measure the amount of a substancein a solution, such as serum. The assay uses a solid-phasetype of enzyme immunoassay to detect the presence of a ligand in a liquid sample using antibodies directed against the protein to be measured.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The device should be fully automated and easy to operate with 8 and 12 channel manifold. • It should be capable to wash flat, round and V bottom plates and strips. • It should have large display along with more than40-50 program storage facility. • System should have calibration facility. • System should have warning/alarm for full waste container and empty wash bottle. • Residual volume after washing should be < 2ul. • It should have specially designed peristaltic pump to dispense 50 - 400 µl. • It should be supplied with waste container, wash bottle and rinse bottle of capacity 2 liters with tubings. • It should have option of programming wash cycleswith capacity for storing at least 50 wash protocols. • Cross wise aspiration, overflow washing and bottom washing. • Bichromatic/Optics with six standard wavelengths for ELISA kits. • Trichromatic Light source. • Internal Printer with port for external printer. • Should read ELISA Plate Horizontally A to H and vertically 1 to 12. • Photometric Accuracy should be ±3%. • Should have a resolution of 0.001 Abs. • Print out of whole plate in Matrix Format. • Linear measurement range 0 to 4 Absorbance unit.

		• 8 filter wheel capacity with Interference. • Filters of 405, 450, 492, 620 nm with at least 4 extra positions within the range of 400-750 nm.
2.2	**User Interface**	Compatibility with external Printer
2.3	**Software and/or standard of communication (Wherever required)**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Should maintain nominal temperature and theheat should be disbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
	4. ENERGY SOURCE	
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz
4.2	**Battery operated**	Online UPS with minimum one hour back up
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spareparts(main ones); Consumables/ reagents (open, closed system)**	1) Paper rolls for printer- 10 nos. 2) Online UPS for minimum one hour back up
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ...); Performance andsafety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.

		4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in eachquarter
10. DOCUMENTATION		
10.1	**Operating manuals, servicemanuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied inEnglish/Hindi language along with machine diagrams. 2) Service and operation manuals (original and copy) to beprovided. 3) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of essential spare/ accessories, reagents/all other consumables along with their part number and cost should be quoted.
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent tobe provided;
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed.

ELECTROPHORESIS ANALYZER		
Version no.:		02
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Electrophoresis analyzer IVD
GMDN Code		57837
GENERAL		
1. USE		
1.1	Clinical Purpose	An electrically-powered automated laboratory instrumentor system intended to be used for the qualitative and quantitative in vitro determination of various molecules (e.g., DNA, RNA, proteins) in a clinical specimen based on their size, ionic charge and/or rate of migration through an electrically charged field.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. Technical Characteristics		
2.1	Technical Characteristics(Specific to this type of device)	• Should be able to undertake multiparametric analysis like serum, protein, isoenzymes, immunofixation. • Automated sample application and sequential processing of each step of electrophoresis with disposable applicators • Gel imaging, interpretation and reporting software should be available with the system • The system should use deuterium lamp with optical fibers for emission and reception. • The system needs to have in built tube mixer. • Should have provision for automatic recycling of Buffer and Stainer. • System should have in built reading capacity. • Should be capable of automatically arrange the loading of all the reagents, standardizing furtherthe electrophoretical process. • The instrument should be capable of quality control measures • The through put of the system should be, at least i. Hemoglobin – 8 samples/ hour ii. Protein – 20 samples/ hour • Automatically able to manage the reagents and automatic washing cycle before the switch-off ofthe unit. • Provision for bi-directional LIS interface should be available.
2.2	Software and/or standardof communication	NA

	(wherever required)	
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (in mm)	NA
3.2	Weight	NA
3.3	Noise	NA
3.4	Heat Dissipation	NA
3.5	Mobility/Portability	Stationary lab Installation
4. ENERGY SOURCE		
4.1	Power input	220VAC +/- 10%, 50 Hz.
4.2	Battery Operated	Online UPS system with minimum one hour back up.
4.3	Protection	Internal electrical safety
4.2	Power consumption	As per Manufacturer/Supplier specified
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	Accessories, (mandatory,Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	1. To be supplied with computer (minimum i5 processor,500 GB HDD and 4 GB RAM), A4 size laser printer and appropriate bar code reader 2. Start-up kit for at least 200 tests should be provided. 3. Online UPS system with minimum one hour back up
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterilityissues	As indicated by Manufacturer
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary, ..);Performanceand safety standards (specific to the device type);Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature,	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.

	values, quality, tolerance	
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	Training of staff (medical,paramedical, technicians)	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in eachquarter.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, othermanuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Certificate of calibration and inspection. 4. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of Vendor and local service agent needsto be provided
11.2	Recommendations or warnings	Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medical device needs to be mentioned.

Turbidometer		
Version no.:		01
Date:		August 2023
Done by : (Name, Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	The turbidimeter is an instrument used for measuring the turbidity of a liquid by determining the degree to which particles suspended in the solution decrease the intensity of light lost as a beam is passed through it.
1.2	**Used by clinical department/ward**	Clinical Lab
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Material should be of high-grade SS (MS-304) 2. Should be benchtop type with LED/LCD display. 3. Suitable for measurement even for colored samples. 4. Range- 0-1000 NTU in four ranges minimum. 5. Resolution should be 0.01 NTU or better. 6. Accuracy: +/- 2 percent of full scale 1 and 1000 NTU 7. The detector should be photodiode. 8. Should have tungsten lamp light source. The lamp life should be minimum for 1 Lakh readings. 9. Measuring modes – Normal, Average & Continuous. The range selection should be automatic. 10. Should be operable in both electric and re-chargeable batteries mode.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA

3.3	**Noise (in dBA)**	Noise-free system
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Tabletop
4. ENERGY SOURCE		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should be supplied with cuvettes and cuvettes stand.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements:**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.

	nature, values, quality, tolerance	
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. Service and operation manuals (original and Copy) to be provided; 3. Advanced maintenance tasks documentation; 4. Certificate of calibration and inspection.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

HbA1C ANALYSER		
Version no.:		01
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Glycated haemoglobin (HbA1C) analyzer IVD
GMDN code(s)		35968
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the quantitative measurement of glycated haemoglobin(HbA1c), also known as glycolhaemoglobin, glycosylated haemoglobin or glucosylated haemoglobin, in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type ofdevice)**	• Automated integrated system for HbA1c testing. (HPLC based preferably) • Should have LED light source of wavelength (400-800) nm. • Should have automatic mixing by using motor, if required. • Should have automatic calibration system. • Should provide NGSP/IFCC certificate for equipment at the time of installation. • System should have a throughput of 40 test/hour. • Measuring range: HbA1c 3-20%. • High precision, CV ≤5% • Should have inbuilt battery backup. • The system should have provision of bi-directional data flow. • The equipment should have digital display unitand PC interface facility. • The system should be equipped with an automated barcode/QR code reading facility
2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA

3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz
4.2	**Battery operated**	Should have inbuilt battery backup
4.3	**Protection**	Internal electrical safety
4.4	**Power consumption**	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard,optional); Spare parts (main ones); Consumables/reagents(open, closed system)**	Should provide Sample rack – 1 No, Pipette rack – 1 No, Printer rolls – 2 Nos, necessary pipettes and any other additional accessories required to perform the HbA1C test.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience(air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterilityissues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary); Performance and safety standards (specific to the devicetype); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality,tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical,**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits.

	technicians)	
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits at least one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals (original and Copy) tobe provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier, and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

URINE ANALYSER

Version no.:		1
Date:		August 2023
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Urine Analyzer IVD, Laboratory
GMDN code		35918
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of various chemical and cellular constituents of a clinical urine specimen, which typically include bilirubin, glucose, haemoglobin, ketones, nitrites, pH, protein, urobilinogen, specific gravity, blood, red cells, white cells, casts, crystals, sperm, and/or microorganisms (e.g., bacteria).
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Should be able to analyse multiple Parameters: Leucocytes, Nitrite, Urobilinogen, Protein, pH, Specific gravity, microalbumins, Ketones, Bilirubin, Glucose etc. • Should be portable, fully automated integrated urine analyzer. • Should have a throughput of minimum 100 samples / hour. • Random access for individual samples • Memory: patient test results minimum 1000 and QC test results: 50. • Provision for report printing • QC should be based on test parameters. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility
2.2	**User's interface**	• Display: touch-screen LCD • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/or standard of communication (wherever required)**	Inbuilt

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary Lab Installation
4. ENERGY SOURCE		
4.1	**Power Requirements**	Power Supply: 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	Yes
4.4	**Protection**	Internal electrical safety
4.5	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts(main ones); Consumables/ reagents (open, closed system)**	1) Thermal Paper 10 rolls. 2) 1000 test strips to be provided. 3) Calibration strip 2.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical,paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits.

9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 03 years 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration androutine maintenance. 3) Service and operation manuals (original and copy) to be provided. 4) Advanced maintenance tasks documentation. 5) Certificate of calibration and inspection;
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost.
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed.

LABORATORY INCUBATOR

Version no.:	01
Date:	
Done by: (Name/Institution)	HCT/NHSRC

NAME, CATEGORY AND CODING		
GMDN name		NA
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Incubators are designed to provide the appropriate environmental conditions (e.g., temperature, humidity, gas concentration) necessary for certain laboratory tests or procedures e.g., bacterial and fungal culture, incubation of ELISA plates etc.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Inner chamber made up of Stainless steel make of SS-304 grade, full length inner acrylic security glass door. • Inner Chamber Capacity: Minimum 120 L • Heat and Corrosion resistant, good quality durable metal housing care. • Triple wall with special grade glass wool insulation. • Temperature range, ambient to 80°C, ±1°C resolution. • Controller/Digital indicator for Temperature and time. • Adjustable over-temperature protection controller to ensure that the Incubator does not go beyond the set temperature and maintains the desired temperature. Should have auto-cut off facility. • Programs stored on power failure so that when power is restored, equipment continues to function on the previous program.
2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	Inner Chamber Capacity: Minimum 120 L
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism

3.5	**Mobility, portability**	Stationary lab installation
4. ENERGY SOURCE		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	Internal Electrical Safety
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Gloves different sizes. 2 or 3 shelves made of stainless steel
6. ENVIRONMENTAL AND DEPAR TMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 03 years 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Advanced maintenance tasks documentation. 4. Certificate of calibration and inspection. 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

HOT AIR OVEN

Version no.:	01
Date:	August 2023
Done by: (Name/Institution)	HCT/NHSRC

NAME, CATEGORY AND CODING

GMDN name	Forced-air laboratory oven
GMDN code(s)	21087

GENERAL

1. USE

1.1	**Clinical purpose**	A mains electricity (AC-powered) device with a heating chamber designed to provide fan-assisted convection to ensure a homogenous temperature profile in the chamber. It is used for laboratory procedures that involve drying, heating, and sterilizing objects.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory

TECHNICAL

2. TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	• Thermostatically controlled, temperature range ambient to 250°C with fine and coarse adjustment, with fan, digital display. • Volume of interior housing: Approx.- 180-400 Liters. • Housing: preferably stainless steel • Heat and Corrosion resistant, good quality, durable • Metal housing care • Stainless steel (SS-304) interiors with supports on three sides, adjustable slots and removable three shelves. • Fan convection to ensure uniform temperature, fitted with load indicator and safety thermostat take over indicator lamp. • Built-in timer with temperature control for to set the sterilization cycle. • Temperature variation +/-1 deg C, LCD/LED indicator.
2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required)**	NA

3. PHYSICAL CHARACTERISTICS

3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Stationary Installation

4. ENERGY SOURCE

4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	Internal Electrical Safety
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Racks with different sizes, Gloves different sizes, Digital temperature controller and indicator.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Not applicable.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	As specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 03 years, including all spares. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.

10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

VERTICAL AUTOCLAVE		
Version no. :		1
Date:		August 2023
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		NA
GMDN code(s)		NA
GENERAL		
1 USE		
1.1	**Clinical purpose**	An airtight vessel used for sterilizing laboratory equipment, culture media and decontaminating biohazardous waste with moist heat at high temperatures and pressure.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2 TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specificto this type of device)**	• Rust-proof 304 grade stainless steel. Triple walled construction. • Minimum chamber Capacity :100 L • Adjustable pressure range- 15-20 psi with accuracy +/- 1 to 3 psi. • Hydrostatically tested to withstand 2.5 times the working pressure. • Sealed with Neoprene/Silicon long-lasting and durable gasket. • Mounted on 304 stainless steel frame with ground leveling flanges • Display for temperature, pressure, and time. • Temperature and pressure cut-off device. • Auto cut-off at low water level • Cylindrical construction. • Equipment should have separate steam release valve and drainage system. • Minimum of two safety valves with auto-release.
2.2	**User's interface**	Display for temperature, pressure and time
2.3	**Software and/ or standard of communication (wherever required)**	NA
3 PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Portable
4 ENERGY SOURCE		
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz.

4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by Manufacturer
5 ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard,optional); Spare parts (main ones); Consumables / reagents (open, closedsystem)**	• Automatic Pressure Control Switch -2 no. • Automatic Water Cut-off Device -2 no. • Micro Processor PID Controller with Timer & Auto Stop Facility • Digital Pressure Indicator-2 no. • Perforate basket (rust-free stainless steel) • Cord-plug-2 no.
6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity,dust ...)**	Capable of operating continuously in ambienttemperature of -10 to 60 deg C and relative humidity of up to 90% inideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterilityissues**	To be specified by manufacturer.
7 STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the devicetype);Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8 TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature,values, quality, tolerance**	As specified my manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits.
9 WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in each quarter.
10 DOCUMENTATION		

10.1	**Operating manuals, service manuals, othermanuals**	Should provide 2 sets (hardcopy and soft-copy) of: - 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) Service and operation manuals (original and copy) to be provided. 3) Advanced maintenance tasks documentation. 4) Certificate of calibration and inspection
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost.
11 NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs should be adequately displayed.

MECHANICAL MICROPIPETTE		
Version no.:		01
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Mechanical micropipette IVD
GMDN code(s)		65710
GENERAL		
1. USE		
1.1	**Clinical purpose**	A manually operated in vitro diagnostic device designed to withdraw, transfer, and inject minute volumes of fluid materials (e.g., microlitres or smaller).
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Single channel microliter pipettes. 2. Fully autoclavable (121 °C); UV-resistant material. 3. Three defined stops (single-button operation preferred): - take-up from the first stop - dispensing and blow out - tip ejection. 4. Should have volume range of 1 µl to 50 µl. 5. Easy and safe tip ejection mechanism. 6. Fixation of adjusted volume. 7. Slim pipette shaft.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE		
4.1	**Power requirements**	**NA**
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Disposable Tips (different volume comparator)
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Sterilization required.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	NA
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams;
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

CLASS-II BIOLOGICAL SAFETY CABINET		
Version no.:		01
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Class-II Biological Safety Cabinet
GMDNS code(s)		20653
GENERAL		
1. USE		
1.1	**Clinical purpose**	A furniture-like device designed as a partial or total enclosure to provide a class II biosafety level (BSL) to the operator, the product, and the environment during the manipulation of microorganisms and other biological hazardous materials (usually up to category 3 pathogens). It is used for handling cell cultures and human pathogens (e.g., bacteria, viruses, parasites) and other biohazardous materials, extremely toxic agents (e.g., chemotherapy drugs), and also for tissue culture and tumour virus work.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Type: BIOSAFETY CABINET, CLASS II A2 (As per NSF guidelines) • The HEPA filter should have rated efficiency of more than 99% at 0.3 microns. • It should provide laminar airflow descending vertically downwards. • The motor for the air flow should have automated setting for the air flow speed to ensure continuous safe working condition. Air flow should be as per NSF regulation (Class II A2) • Fluorescent lamp for lighting of the interior of the cabinet. Light Intensity: 650 lux or more over the entire work surface. • Construction: Main body, side and rear panel: Electro - galvanized Steel or Mild Steel, oven baked epoxy powder coated finish. The internal cabinet material should be 300-series stainless steel and should provide a seamless and scratch free worksurface. • Front panels construction: Removable laminated safety and tempered glass for protection against leakage of UV rays and potential hazards materials. • The front sash opening should range between 8-12 inches and should be specified on the cabinet. Incase UV lamp is inbuilt, the closing/opening of the door should automatically be switched off if the front door is open. • Alarm system: Audio visual Safety alarms/safety display

		for low air velocity, faulted exhaust fan and incorrect sash height shall be required to indicate within 15 seconds. • Fluorescent lamp for lighting of the interior of the cabinet. Light intensity: 650 lux or more over the entire work surface. • Switches and indicators: Individual switches and indicator lamps for blower motor, florescent lamp, and UV lamp. • Differential pressure gauge (scale display in Pascals). The cabinet should use a pressure sensor to detect pressure drop across the supply filter. • Other fittings required for Attaching auxiliary services: Electrical outlet socket (5 ampere rating) qty: 2 numbers • Pre Filters: Filtration efficiency of 98% for all types of particle sizes 8 micron and larger. • The equipment should provide product, operator and environmental protection and must be certified to NSF/ANSI 49. The cabinet must have a data plate and NSF certification label. • A data plate(s) indicating the following shall be readily visible on the front of the cabinet: o Manufacturer's name and address o Cabinet model o Cabinet serial number o Type classification o Voltage requirements o Dimensions of cabinet o Method of field certification o Allowable ranges for Downflow Velocity Inflow • The minimum average inflow velocity should be 100ft/min and downflow velocity 50-80ft/min, it may vary according to model. • Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) certification and calibration- at the time of installation and annually during warranty period.
2.2	**User's interface**	Display for various indicators
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	4 feet width
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise level: < 60 dBA.
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.

3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS with a minimum backup time of one hour
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	• Exterior exhaust filter guard • Spare fluorescent lamp.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Advanced maintenance tasks documentation. 4. Certificate of calibration and inspection. 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

LABORATORY SHAKER		
Version no. :		01
Date:		August 2023
Done by: (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		Laboratory Shaker IVD
GMDNS code(s)		65432
GENERAL		
1. USE		
1.1	**Clinical purpose**	An electromechanical in vitro diagnostic device designed to shake/stir samples or mixtures with a rapid and forceful movement. It is used to provide a rapid mixing or to prevent substances comprised of different components from separation or sedimentation because of their different densities.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Non-slip Platform size- minimum 300x300 mm with adjustable roller to accommodate ample in test test tubes, VDRL plates/slides, blood bottles and flasks by clamp and spring holder. • Should have rotation in horizontal plane. • Knob for selecting operation. • Acceleration circuit to prevent sudden start and stop should be available. • Timer adjustable from 0 to 99 min or continuous mode with digital display of RPM and timer desirable. • Noiseless operation • Uniform shaking variable speed upto 180 rpm or more with ± 2 rpm accuracy, heavy duty motor and timer
2.2	**User's interface**	Digital display for RPM and timer
2.3	**Software and/ or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noiseless operation
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No

4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Test tube racks.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. Service and operation manuals (original and Copy) to be provided.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;

11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

RT-PCR SYSTEM		
Version no.:		01
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		NA
GMDN Code		NA
GENERAL		
1. USE		
1.1	Clinical Purpose	RT-PCR is a laboratory technique combining reverse transcription of RNA into DNA (in this context called complementary DNA or cDNA) and amplification of specific DNA targets using polymerase chain reaction (PCR). This is achieved by monitoring the amplification reaction using fluorescence a technique called real-time PCR or quantitative PCR (qPCR). Combined RT-PCR and qPCR are routinely used for analysis of gene expression and quantification of viral RNA in research and clinical settings.
1.2	Used by clinical department/ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. Technical Characteristics		
2.1	Technical Characteristics (Specific to this type of device)	• Tabletop model. • Open system to accommodate TaqMan, SYBRgreen and all other fluorescent dye-based chemistries. • The system should be flexible to use micro well plates, individual PCR tubes and PCR tube strips. • Peltier based atleast 48 well block/Rotor or bettersystem. • It should have excellent thermal (Temperature range: 4 to 99 deg C; Temperature accuracy: ± 0.25 Deg C) and optical performance. • Sensitivity: Detection of 1 copy of template anddifferences as small as 1.5-fold in target. • It should have a fast ramp rate for heating andcooling. • The system should be easily calibrated with new dyes without any change filter or hardware. (Should have pre-calibrated for minimum 7 dyes). • CCD camera with halogen/LED/ Photodiode/ CMOS and at least sixexcitation and six emission filters to perform multiplex assays. • Option for melt curve analysis using high resolution software. • The system should facilitate for calibration

		ofmultiple dyes at installation. • It should have 5 channels (5plex) for optical detection: Green channel (Excitation: 470 ± 10 nm, Detection: 510 ± 5 nm), Yellow channel (Excitation: 530 ± 5 nm, Detection: 557 ± 5 nm), Orange channel (Excitation: 585 ± 5 nm, Detection: 610 ± 5 nm), Red channel (Excitation: 625 ± 5 nm, Detection: 660 ± 10 nm), and crimson channel (Excitation: 680 ± 5 nm, Detection: 712 high pass nm). In addition, the software should allow creation of new excitation/detection wavelength combinations, as per requirement. • There should be enough excitation and emission filters to cover majority of dyes. • The system should be flexible and compatible with reagents, chemistries and plastic ware from third party vendors. • The system should have online UPS system with minimum 2-hour backup. • HRM analysis should be supported by thermal resolution of 0.02°C, high data-acquisition rates, and appropriate HRM software. • It should support multiple PCR tube formats and strips as per standards. • It should have digital display. • It should have a small footprint (Width: <40 cm; Height: <30 cm; Depth: <45 cm and Depth (door open): <55 cm). • Software: Software should be latest, compatible with window OS system and should be compliant or matching with the hardware. • Should be able to generate reports and analysis reports in both excel or pdf format. • A quick and automated temperature accuracy testing provision should be available.
2.2	**Software and/or standard of communication (wherever required)**	1. Unlimited user licenses and individual user management provision should be available for the software. 2. Analysis workstation should be of latest configuration with a color printer.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (in mm)**	As per the manufacturer
3.2	**Weight**	As per the manufacturer
3.3	**Noise**	NA
3.4	**Heat Dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility/Portability**	Portable
4. ENERGY SOURCE		
4.1	**Power input**	220 + - 10% VAC, 50 Hz

4.2	**Battery Backup**	Should be compatible with online UPS (2KV).
4.3	**Protection**	Internal electrical safety
4.4	**Power consumption**	As specified by manufacturer
5. ACCESSORIES, SPARE PARTS AND CONSUMABLE		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	1. A laptop with latest configuration and with operating system compatible with the dedicated softwareshould be provided along with the system. 2. The system should come with – a. RT-PCR instrument, b. Rotors stand/holder, c. USB and RS-232 serial cable d. PCR tubes (1000 Nos.) and strip tubes with caps(1000 Nos.). e. Dyes should be provided with the system. f. Reagents for 500 reactions should be providedwith the instrument.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (Air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As per manufacturer's recommendation
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	As indicated by manufacturer and compatible electricalaccessories as per standard Indian set-up.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operationchecks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided on installation and duringPreventive Maintenance visits.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 3 years 2. Preventive maintenance visits at least one in each quarter.

10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. List of equipment and procedures required for localcalibration and routine maintenance. 3. Service and operation manuals (original and Copy) tobe provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation fromgovernment hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their partnumber and cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and localservice agent to be provided.
11.2	Recommendations or warnings	Any warning signs should be adequately displayed.

Spirometer		
Version no.:		01
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. Use		
1.1	**Clinical purpose**	A spirometer is an apparatus for measuring the volume of air inspired and expired by the lungs.
1.2	**Used by clinical department/ ward**	Respiratory Medicine Department, COPD clinic, Internal Medicine
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	1. The spirometer should be portable and should have facility to interface for desktop / Laptop Computer. 2. The microprocessor/computer should be capable of accepting patient identification number (i.e age, height, gender and date). 3. It should be able to monitor the following parameters: • Spirometry & Flow Volume Parameter • Maximum Ventilation Volume • Pre & Post Bronchodilator comparison • Lung Volumes & Sub – divisions • Broncho Provocation Test. 4. Flow meter: –Bi-directional digital turbine or Pneumotach. 5. Should incorporate Electronic Barometer & temperature Sensors, for Automatic BTPS Correction. 6. The device should provide real time flow volume and volume – time traces on computer/microprocessor screen.
2.2	**User's interface**	Manual

2.3	**Software and/or standard of communication (wherever required)**	In-built
	3. Physical characteristics	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
	4. Energy source (electricity, Ups, solar, gas, water, co2)	
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	UPS with power backup of at least 30 minutes
4.3	**Protection**	NA
4.5	**Power consumption**	As specified by manufacturer
	5. Accessories, spare parts, consumables	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	1. Computer interfacing package, cables and software 2. Disposable mouth pieces-100
	6. Environmental and departmental considerations	
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer.
	7. Standards and safety	
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.

	(specific to the device type); local and/or international	4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. Training and installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and maintenance		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

MISCELLANEOUS ITEMS

S.No	Title	Specification	Image
1.	**Neubauer's Counting Chamber**	**Description:** Chamber used to count number of cells. • Material of slide: thick crystal • Size of counting grid: 3 x 3 • Number of square subdivisions in counting grid: 09 • The slide should have a central area where cell counts are performed with inbuilt marker lines dividing the central square into 25 small 100 squares. • 25 squares should be subdivided into 16 smaller squares adding up to a total of 400 small squares in the central area. • Provision to fit a glass cover of a squared glass.	
2.	**ESR Tubes with Stand**	**ESR Tubes:** Color: Transparent Material: Polypropylene Nominal capacity: 0.5 milliliter **ESR Stand:** Material- Good quality steel Holding Capacity- 06 Tubes or more