Annexure B Sheets
(Clause by clause compliance to be enclosed separately for items quoted with End user certificates from users with Contact and address)

ANNEXURE B

SPECIFICATIONS FOR BLOOD BANKS
&
BLOOD COLLECTION SEPERATION UNITS

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Specifications -As per Sheets enclosed in Annexure B

Annexure B

MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)	
1.	**Blood Mixer and Collector (Blood Collection Monitor)**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Mixers and associated devices
GMDN code	CT422

GENERAL		
1	USE	
1.1	**Clinical purpose**	The system is used to collect donated blood from the donor at the same time mixing the blood for quality collection of blood.

TECHNICAL		
2	TECHNICAL CHARACTERISTICS	
2.1	**Technical characteristics (specific to this type of device)**	It is meant for stationary and mobile use. Gentle end to end mixing and control of collection time to give high quality blood suitable for all blood bags. **Construction:** LED indication on commencement of collection. LED indication and audible alarm at the end of collection. Indication of time taken for collection. Indication of blood flow with audio alarm when blood flow is higher or lower than desired. Continuous display of collected volume, flow and time during collection. Automatic clamping at termination of preset volume collection. Automatic release of bag when lifted. Continuous agitation of blood bags during collection: 12-16 rpm. Equipment carry case for BCM should be provided for portability. Input port cable with 15 Plug and six way output terminal strip for two outlets. Volume Settings: Pre-selection of volume to be collected. Tarring of bag volume before collection. Automatic storages and recall of set volume. Measure volume with best accuracy. Preset value: 350/450 mL. Tarring Range: 0-600 g.
2.2	**Capacity**	NA
2.3	**Settings**	Manual
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	

3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220-240V AV, 50Hz, 440V three phase as appropriate fitted with indian plug.
4.2	**Battery operated**	Should operate on mains as well as rechargeable battery. On battery it should operate for a minimum of 5-8 hours.
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	Resettable over current breaker shall be fitted for protection.
4.5	**Power consumption**	NA
4.6	**Voltage regulation**	Suitable automatic voltage regulator/stabilizer meeting ISI specifications should be supplied. Broad specifications are: Automaatic type input 150-280V, output 220V ±7%, 50Hz. Single phase, AC with automatic 2-4 sec cutt-off and 6-9 minutes restart delay. Quick start arrangements for bypassing the start delay. Suitable MCB on input voltmeter and indicators on Front Panel.
4.7	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	The unit shall be capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.

6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 year
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.

11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

2. Binocular Microscope-Specifications

Equipment Specifications for BINOCULAR MICROSCOPE COMPOUND

1 Description of Function

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
1.1	Compound microscopes consists of two or more than two magnifying lenses.One can view individual cells, even living ones. It has high magnification		

2 Operational Requirements

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any

2.1	System complete with illumination system is required.		

3 Technical Specifications

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
3.1	Body :Binocular, sturdy, stable base body with focus adjustment controls		
3.2	Eye piece :Paired, high quality, (the image of the object as seen through the binocular eyepiece should be well defined centrally in at least 2/3 field of view), achromatic, widefield, 10x without inbuilt pointer. The eyepiece should be aplatanic and have a minimum field number of 18. Diopter adjustment must be present on one/ both eye pieces or on the eye piece tube		
3.3	Objective :Two objectives10x,40x Imported 10x and 40x objectives should have numerical apertures of 0.25 and 0.65 respectively and should be of spring loaded type or otherwise. Unbreakable containers to be provided for storing the objectives. All objectives should be wide field, achromatic and parfocal. Making for the Objectives :Each objective should be engraved with the following informations:- • Name of the manufacturer • Magnification and numerical aperture, for example, 10x/0.25 in changing from one objective to another or reintroducing the same objective by rotation of the nosepiece, the object at the center of the field should not appear displaced by more than 0.02 mm in the object plane in any direction.		
3.4	Nose piece:Revolving nose piece to accommodate a minimum of three objectives with click stops. It should be provided with ribbed grip for easy rotation mounted on a precision ball bearing mechanism for smooth and accurate alignment. Extra ports if any should be fitted with dust proof metallic/ebonite caps.		
3.5	Stage Uniformly horizontal, mechanical stage having dimensions of length 140 mm (+/- 20mm) with fine vermier graduations (minimum reading accuracy of 0.1 mm). the stage should be provided with spring loaded slide holder for exact positioning of specimen/ slide. It should be designed with convenient sub-stage vertical coaxial adjustment for slide manipulation. The stage should have ball-bearing arrangement to allow smooth travel in transverse directions i.e. 80 mm (+/-5mm) and front to back direction, 50mm (+/-5mm)		
3.6	Sub-stage condenser:Abbe-type condenser, numerical aparature (N.A.) 1.25 focusable with rack and pinion arrangement incorporating an aspherical leps and an iris-diaphragm. The condenser should have a filter holder and removable/ swing in/ out blue filter (suitable for bright field Microscopy).		
3.7	Sub-stage illuminator: 1.The system should have a build-in variable light source (Illuminator). This light source		

	should have a 20 W, 6 V Halogen lamp. The circuitry for the light source should include a constant voltage supply. The system should be provided with a step down transformer and an on-off switch and intensity control. The lamp should be provided with a lamp socket which has the facility for easy replacement of the bulb, 2. Power Supply a. Voltage 220 V, 50 Hz AC b. Should have one on-off power switch, 3 core power cord with a 3 point male plug. 3. The system should have an inbuilt protective/ safety device to withstand fluctuations of voltage from 140 V to 280 V 4. A plano-concave mirror in fork mounting should be supplied which would be attachable to the base for field use. (where power is not available). 5. The fuse for the halogen lamp should be easily accessible to the operator 6. The Illuminator should have a build-in field diaphragm for Kohler illumination		
3.8	Eye piece tubes:Binocular eye piece tubes, inclined at 45 degrees, rotatable through an angle of 360 degrees, having inter-pupullary distance range of 54-74 mm or wider, covering the above mentioned range		
3.9	Focusing knob:Co-axial coarse and fine focusing knobs capable of smooth fine focusing movement over the full range of coarse travel. The fine focusing movement should have sensitivity of two microns or less (finer) over the entire coarse focusing stop safety arrangement should be provided.		
3.10	General 1.All optical parts including objectives, eye pieces and prisms should have anti-reflective coating which also gives anti-fungal property. 2.All metallic parts should be corrosion-proof, acid-proof and stain-proof 3.Working manual should be provided with each microscope 4.One no.of anti static cleaning brush should be provided with each Microscope for cleaning purpose. 5.Each Microscope should be supplied with Blue filters. The Blue filter should be packed in the ox and not fixed on the Microscopes.		

4 System Configuration Accessories, spares and consumables

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
4.1	System as specified-		
4.2	Each microscope should be supplied with spare parts as under: •Halogen bulb, (6volts, 20w) – 6 Nos. •Fuses – 6 Nos.		
4.3	All consumables required for installation and standardization of system to be given free of cost.		

5 Environmental factors

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
5.1	The unit shall be capable of being stored continuously in ambient temperature of 0 -50deg C and relative humidity of 15-90%		
5.2	The unit shall be capable of operating continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%		

6 Power Supply

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
6.1	Power input to be 220-240VAC, 50Hz fitted with Indian plug		
6.2	Suaitable voltage corrector/stabilizer		

7 Standards and Safety

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
7.1	Should be USFDA or European CE approved product		
7.2	Two years warranty, 3 years comprehensive CMC should be available with service centers in close proximity.		

8 Documentation

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
8.1	User/Technical/Maintenance manuals to be supplied		
8.2	Certificate of calibration and inspection from factory.		
8.3	List of important spare parts and accessories with their part number and costing.		

MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)	
3.	**Cell Counter (Automated Hematology Analyzer)**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Haematology analyser IVDs
GMDN code	CT561

GENERAL		
1	USE	
1.1	**Clinical purpose**	To determine the count of various blood cells and hemoglobin estimation for the screening of blood donors.

TECHNICAL	
2	TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	Should be a fully automated hematology 3 part differential analyzer with option to print the results with histograms of basic 8 parameters like RBC, WBC, Platelets, Hemoglobin (HGB), MCH and others. The reportable RBC indices should be: Total RBC, HCT, HGB, MCV, MCH, MCHC and user definable settings for RDW-CW and RDW-SD, RBC count linearly should be above 6.5 X 106/uL. Reportable platelets indices should be: Total platelet count, MDW and P-LCR. The system should give the differential count as lymphocytes, mix population and neutrophils in percentage as well as absolute count. **Construction:** The system should have autoprobe wiper to clean the sample probe automatically after sample aspiration. The system should have automatic floating threshold for correct separation of WBC, RBC's and platelets during overlap of microcytosis / large platelets. The system should use cynide free reagents.Should be able to perform all blood counts from whole blood and blood components at different dilutions for the purpose of quality control. **Sample type:** Venous blood, peripherals blood, pre-dilution peripherals blood and various dilutions of blood. **Rapid result turn around time:** upto 60 samples per hour throughput. **Printer:** Built in thermal printer can be connected to external computer and printer. **Display:** large color LCD, show all parameters and histograms at same sceen. **Calibration:** Three test modes offer auto and manual calibration, provide original calibrator and control. **Interface:** USB with printer, mouse and keyboard, internet port.
2.2	**Capacity**	Storage capability for detail results including histograms .
2.3	**Settings**	Manual, User definable
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220/240V 50Hz, single phase, with inbult FIE safety against high load voltage.
4.2	**Battery operated**	NA

4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	On line voltage corrector of appropriate rating as per standard configuration.
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately. Should specify the rates of all the consumables and reagents.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Reagents for validation/training of users in operation and installation shall be provided by the manufacturer free of cost. Cost of reagents for routine operation to be quoted separately as mentioned below.
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

Cost of Reagents

Bidders are also required to quote for cost of reagents. The evaluation shall be carried out considering 15000 tests per machine for 3 years including every day start up and shut down each (total 1100 start up and shutdown in 3 years). The quotation as above, should be submitted in sealed envelope containing dully filled format as given below and super-scribed it with "Tender Ref. No. 28 - quote for Cost of Reagents for Blood Cell Counter" to the Tender Inviting Authority up to the scheduled date and time for submission of physical EMD and Technical Bid.
It is clarified that no. of tests mentioned above including start-ups and shut downs each is only indicative and shall be used for the purpose of evaluating net cost of machine. **The actual purchase of reagents by respective ordering authorities may vary as per their actual requirement.**

Price Schedule for Cost of reagents and start-ups and shutdowns for use with Fully Automatic Blood Cell Counter

Description	Price/test (Rs.) incl. one startup & one shutdown daily	Sales / VAT payable if contract is awarded	Total cost of 5000 tests (inclusive of Sales tax / VAT)
Year 1 cost of 5000 tests			
Year 2 cost of 5000 tests			
Year 3 cost of 5000 tests			
		Grand Total	

Cost of reagents to perform 5000 tests in 3 years including 1100 start ups and shut down each.
Note: Above cost shall be added to the machine cost which is to be submitted online and total bid price shall be evaluated to arrive at L-1 price.

MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)	
4.	**Donor Couch**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	NA
GMDN code	NA

GENERAL		
1	USE	
1.1	**Clinical purpose**	Blood Donor Couch is a completely automatic enveloping, variable tilt chair and specially designed to make blood withdrawals easier, safe and functional, and also for other diagnostic and therapeutic areas.

TECHNICAL		
2	TECHNICAL CHARACTERISTICS	
2.1	**Technical characteristics (specific to this type of device)**	**Construction:** Variable positioning for either arm with comfortably wide arm-rests with swinging out as well as up and down moving facility. Reclining and upright body positions with a smooth shifting to any position. Both sides should have supporting brackets for material required for blood collection. Ergonomically designed comfortable chair type for donor comfort. mattress should be comfortably cushioned with elegantly thick washable upholstery. Seat, back rest and leg rest size designed for donor comfort. It should have step less electric remote controlled height adjustment. Easily tilted to head low position, electrically operated. Should have two motor system each for back section and leg section adjustment. Should be mobile with lockable wheels. Comfortable working level for the operator. Lifting Capacity: Approx 200 Kg

2.2	**Lifting Capacity**	Approx 200 Kg
2.3	**Settings**	Manual
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input supply 220-240V, 50 Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA

6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	NA
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	NA
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.

10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
5.	**Dielectric Tube Sealer**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	NA
GMDN code	NA

GENERAL		
1	USE	
1.1	**Clinical purpose**	Blood Bag Tube Sealer is a compact equipment to seal the Blood Bag pilot tubing.

TECHNICAL		
2	TECHNICAL CHARACTERISTICS	
2.1	**Technical characteristics (specific to this type of device)**	The system should be heavy duty and be able to seal the blood bag etc quickly and effectively. Should be simple to handle. System should gently seal the tubing with no hemolysis using radio frequency. Should be capable of making wide seal of 2 mm thickness. System should run on both mains and battery (more than 10hrs back up and charger). Back up battery should seal more than 500 seals on PVC-tubes in continuous mode. **Construction:** Should be for bench-top use. Sealing trigger should be automatic. Should have extended portable hand unit sealing hand should be with coaxial cable of 1.5-2.0 meter. Should have indication lamps for "Sealing Process" on handle as well as main unit. No warm up time should be required. Should ensure easy separation of tube segments after the sealing. Electrodes should be well protected by a cover. Sealing Time: Should not be more than 2 seconds.
2.2	**Settings**	Manual
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	Built in
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**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220-240V, 50Hz AC single phase or 380-400V AC, 50Hz three phase fitted with appropriate indian plugs and sockets.
4.2	**Battery operated**	System should run on both mains and battery (more than 10hrs back up and charger). Back up battery should seal more than 500 seals on PVC-tubes in continuous mode.
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	Suitable autovoltage corrector with spike protector should be available.
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	The unit shall be capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

1	General Spefications:6. Blood bag Weighing Device **Blood Bank Scale**.	
	• LED or LCD displays of Weight and Volume with accuracy of ± 1 mt / gm • Helps better balancing of refrigerated centrifuge • Tare provision to account for the weight of the blood bag • ABC Mounded body • Auto Calibration Certification from Weights and measures required. Use-for weighing Blood Bags	
2	WARRANTY 2 YEARSAND MAINTENANCE	
2.1	**Warranty**	2 years

2.2	**Maintenance tasks**	3 years CMC
2.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
3.	DOCUMENTATION	
3.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
3.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
4	NOTES	
4.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
4.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

Equipment Specifications for Cold Box, Small, Blood Bank

1 Description of Function

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
1.1	Cold Box is essential to carry whole blood from individual donors to blood bank or from blood bank to point of use within safe temperature range (2 to + 10 deg C) for a particular period known as cold life of the product		
1.2	Purpose of Equipment: To carry whole blood from individual donors to blood bank or from blood bank to point of		

	use		

2 Operational Requirements

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
2.1	The small cold box , long range should be able to keep the Blood Bags safe while transporting to long distances for longer hours of time. Blood storage capacity of 10 units is required.		

3 Technical Specifications

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
3.1	External surface and internal lining material LLDPE-(Linear Low Density Polyethylene)		
3.2	Insulation material CFC-free Polyurethane		
3.3	Insulation thickness-90-120mm		
3.4	Cold life without opening 90-160hrsat+ 43 degree C(or better)		
3.5	Cold Box shall be CFC free and shall be marked CFC Free on the outside).		
3.6	Each cold Box shall contain adequate icepacks		
3.7	External dimensions 50x55x47 in cms		
3.8	Internal dimensions 27x24x26 in cms		
3.9	Lid type- Hinged		

4 System Configuration Accessories, spares and consumables

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
4.1	Unit as specified		

5 Environmental factors

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
5.1	The unit shall be capable of being stored continuously in ambient temperature of 0 -50deg C and relative humidity of 15-90%		
5.2	Maximum Ice Melting Rate: More than 15 hrs cold life per kg of ice melted at 43 °C		

6 Power Supply

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
	None		

7 Standards and Safety

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
7.1	Inspection and Laboratory Test Procedure to be carried out as per WHO Standard Test Procedure: B4/PROC/4		
7.2	The equipment should Conform to WHO Specifications B4/BC1		
7.3	Manufacturer should have ISO certification for quality standards.		

8 Documentation

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
8.1	Manufacturers certification of compliance of test procedures as per WHO Standards Test Procedures.		
8.2	Inspection Certificate from manaufacturer to be complying with WHO specification as specified above.		

8.Equipment Specifications for Cold Box, Large, Blood Bank

1 Description of Function

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
1.1	Cold Box is essential to carry whole blood from individual donors to blood bank or from blood bank to point of use within safe temperature range (2 to + 10 deg C) for a particular period known as cold life of the product		
1.2	Purpose of Equipment: To carry whole blood from individual donors to blood bank or from blood bank to point of use		

2 Operational Requirements

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
2.1	The Large cold box , long range should be able to keep the Blood Bags safe while transporting to long distances for longer hours of time. Blood storage capacity of 50 units is required.		

3 Technical Specifications

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
3.1	External surface and internal lining material LLDPE-(Linear Low Density Polyethylene)		
3.2	Insulation material CFC-free Polyurethane		
3.3	Insulation thickness 100-120 mm		
3.4	Cold life without opening 120-185 hrs at +43 degrees C (or better).		
3.5	Cold Box shall be CFC free and shall be marked CFC Free on the outside).		
3.6	Each cold Box shall contain adequate icepacks		

3.7	External dimensions 70 X 55 X50 in cms.		
3.8	Internal dimensions 50 X 34 X27 in cms.		
3.9	Lid type –Hinged		

4 System Configuration Accessories, spares and consumables

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
4.1	Large Cold Box- Large Range(including integrated lockable fittings)- qty-		

5 Environmental factors

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
5.1	Maximum Ice Melting Rate: More than 10 hrs per 1 kg ice melted during 43 °C cold life test		

6 Power Supply

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
	None		

7 Standards and Safety

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
7.1	Inspection and Laboratory Test Procedure to be carried out as per WHO Standard Test Procedure: B4/PROC/2		
7.2	The equipment should Conform to WHO Specifications B4/BC2		
7.3	Manufacturer should have ISO certification for quality standards.		

8 Documentation			
Sl	**Name**	**Technical Specs quoted by bidder**	**Bidders Deviation if any**
8.1	Manufacturers certification of compliance of test procedures as per WHO Standards Test Procedures.		
8.2	Inspection Certificate from manaufacturer to be complying with WHO specification as specified above.		

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
	9. Manual Plasma Expresser
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Expressors
GMDN code	CT1995

GENERAL		
1	USE	
1.1	**Clinical purpose**	Should be suitable to express blood components (plasma, platelets) from collection container.

TECHNICAL	
2	TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	Should be suitable to express blood components (plasma, platelets) from collection container. Mode of operation: Manual **Construction:** Front panel should be spring loaded to uniform pressure on container causing transfer of fluid. Compression plate should be made to transparent acrylic, durable. Metal used for the equipment should be non corrosive and can be cleaned with antiseptics. Base portion and vertical surface should be made to have better strength and long lasting performance.
2.2	**Capacity**	NA
2.3	**Settings**	Manual
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	Input supply 220-240V, 50 Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.

6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Metal used for the equipment should be non corrosive and can be cleaned with antiseptics. Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	NA
9	WARRANTY AND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation

10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
10.	**Incubator**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING

GMDN name	Laboratory Incubator
GMDN code	CT176

GENERAL		
1	USE	
1.1	**Clinical purpose**	Dry Bath Incubators are designed to accommodate an assortment of interchangeable Heating Block Modules.

TECHNICAL		
2	TECHNICAL CHARACTERISTICS	
2.1	**Technical characteristics (specific to this type of device)**	1) Body: This unit has double walled chamber, with PUF insulation. 2) Interior is made of Stainless Steel (minimum grade 304) and Exterior is either made of Mild Steel finished in powder coated steel or Stainless Steel. 3) The unit has full-length inner glass door and outside metal door with magnetic gasket and lock. 4) This unit is provided with Mesh type trays. 5) Temp. controller: Digital type 6) Temp. range: 1 deg C to 110 deg C 7) Accuracy: 0.3 deg C in the given range 8) Heating Block: 24 holes of 12.7 mm diameter or as selected. 9) Timer: 1 to 60 minutes, digital type
2.2	**Capacity**	NA
2.3	**Settings**	Manual
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	(160-180mm) X (220-240mm) X (80-100mm) ±10% approx
3.2	**Weight (lbs, kg)**	Upto 5 Kgs
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	NA

3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220/240V 50Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY AND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION

(Including Information on the following where relevant/appropriate, but not limited to)

11. Table top centrifuge (Serology Centrifuge)

Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Centrifuge rotor
GMDN code	CT2379

GENERAL		
1	USE	
1.1	**Clinical purpose**	Prepration of samples for clinical/lab analysis.

TECHNICAL		
2	TECHNICAL CHARACTERISTICS	
2.1	**Technical characteristics (specific to this type of device)**	1) Speed Range 500 to 4500 rpm on load with variable speed regulator. 2) It should be fitted with digital timer 0-59 minutes and digital speed indicator; LED/LCD display 3) The machine should be supplied with angle rotor head having 16 tubes of 15 ml capacity. It should be supplied with stainless steel tube carrier, rubber cushions, graduated glass tubes of 15 ml capacity graduated plastic tubes of 15ml capacity. 4) The lid should be double walled, made of steel sheet/ABS plastic injection moulding for extra safety. 5) It should also be fitted with electronic lid lock which should not open when machins is in running condition. 6) The Motor of machine should be fitted with anti vibration pads. 7) Should be well packed in the thermo-cool box.
2.2	**Capacity**	Can accommodate 16 tubes at a time.
2.3	**Settings**	Manual
2.4	**User's interface**	Manual

2.5	**Software and/or standard of communication(where ever required)**	Built in.
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220/240V 50Hz, 1/8 HP Motor of 220V AC
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. Also supplied comlete instruction manual, cord and plug, dust cover, 12 spare rubber cushions, 2 spare fuse and 3 sets of carbons of motor. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.

6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.

11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
12.	**Water bath**
Version no. :	1.0
Date:	10/1/2014

Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Water bath
GMDN code	CT521

GENERAL		
1	USE	
1.1	**Clinical purpose**	A water bath is a device used in the laboratories to incubate samples in water maintained at a constant temperature.

TECHNICAL		
2	TECHNICAL CHARACTERISTICS	
2.1	**Technical characteristics (specific to this type of device)**	Water Bath with MICROPROCESSOR technology 1) Bright temperature display (LED) 2) Seamless, splash-proof keypad 3) Splash-proof mains switch 4) Audible and optical warning signal for the cut-off function 5) Drain screw for conveniently emptying the bath 6) Dry-running protection 7) Removable bottom plate 8) Working temperature range: 20 deg C to 99.9 deg C 9) Temperature stability: ±0.2 ℃ 10) Display: LED 11) Display resolution: 0.1 ℃ 12) Integrated programmer not available 13) Heater capacity: 2000 W 14) Bath opening / bath depth (W x L / D) 50 x 30 / 18 cm 15) Filling volume: 8 to 26 Liters 16) Ambient temperature 5 deg C to 40 deg C

2.2	**Capacity**	NA
2.3	**Settings**	Manual
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	Dimensions (W x L x H) 60 x 40 x 35 cm (max)
3.2	**Weight (lbs, kg)**	Weight 20 kg approx.
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	2000 W
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220/240V 50Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.

6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY AND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.

10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
13	**Blood Bank Refrigerator/ Serology Refrigerated for Blood Storage Unit 50 Bag Capacity**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Refrigerators
GMDN code	CT1897

GENERAL		
1	USE	
1	**Clinical purpose**	A refrigerator for storing whole blood or red cell packs in a blood bank. A refrigerator for storing various reagents and /or patient samples.

TECHNICAL	
2	TECHNICAL CHARACTERISTICS

2	**Technical characteristics (specific to this type of device)**	Compression type refrigerator that uses CFC free refrigerant gas. **Construction:** Internal: Stainless steel (min. 22g) (S.S. V2 A- 1.4301) External: Solid outer Corrosion Resistant (at least 1mm thickness), CFC free insulation Drawers: Roll out type, Stainless steel scratch resistant material, perforated on the bottom for perfect and homogeneous distribution of cold air. The separators, if provided in the drawers, should be such that blood bags are held in a vertical position with the lable side visible. Door: Glass door, Automatic closing of the front door below opening angle of 90 deg C and opening angle limited to 110 deg C, Insulation and gasket should be silicon. Polyurethane insulation should be minimum 80mm thickness. Door opening audio and visual display alarm. **Temperature Range:** 2 deg C to 6 deg C and adjustable with setting accuracy of ±0.1 deg C with set temperature of 4 deg C. User parameter settings: set point, high alarm point, low alarm point, buzzer off time, C/F temperature choice. **Minimum Compressor Starting Voltage:** 22% below nominal voltage **Internal Temperature Control:** Electronic temperature control, range +2 deg C to +6 deg C with setting accuracy of ±1 deg C whatever the load, Fan air cooling. **External Ambient Temperature:** Performs in an ambient temperature of +10 deg C to +40 deg C. **Hold over time:** A full load of blood packs at +4 deg C (±1 deg C) takes at least 30 minutes to rise to above +6 deg C. Internal temperature hold over time in case of power failure should be at least 1.5 hrs. **Cooling Down Time:** A full load of plasma packs at +25 deg C takes a maximum of 13 hrs for all the packs to reach below +6 deg C **Temperature Monitoring:** Digital temperature (LED) display with 0.1 deg C graduation, Temperature recording device, Microprocessor control for operation with integrated audio visual temperature alarm function with digital monitoring display. Independent safety thermostat to avoid negative temperatures. Atleast 2 temperatures sensors: Sensor for temperature monitoring shown on front display, sensor for managing use of compressor. **Temperature recording device:** Visual and audible alarm system indicating unsafe temperatures. Battery backup for alarm system indicating unsafe temperatures. Seven days graphic temperature recorder with range of -10 deg C to +20 deg C with supply of free charts for a period of one year. Ideal compressor running time of 27% at room temperature. Door locks should be available. Audio and visual alarm for variation in temperature, Interior lightening, Auto defrosting.
2	**Capacity**	As required by the blood bank (50 plasma bags of 350/450 mL each)
2	**Settings**	Manual
2	**User's interface**	Manual
3	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3	**Dimensions (metric)**	NA
3	**Weight (lbs, kg)**	NA

3	**Configuration**	NA
3	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
4	**heat dissipation**	NA
4	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4	**Power Requirements**	input voltage 220/240V 50Hz
4	**Battery operated**	NA
4	**Tolerance (to variations, shutdowns)**	NA
4	**Protection**	A line voltage corrector of appropriate rating will form part of standard configuration.
5	**Power consumption**	NA
5	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7	**Product certifications**	European CE or US FDA certified
7	**Quality certifications**	ISO 13485 certified
7	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
8	TRAINING AND	

	INSTALLATION	
8	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8	**Requirements for sign-off**	NA
8	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY AND MAINTENANCE	
9	**Warranty**	2 years
9	**Maintenance tasks**	3 years CMC
9	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	NA
11	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be declared

MPPHSCL/15-16/BB/BCSU/Specifications

MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)		
	14.	**Blood Bank Refrigerator/ Serology Refrigerated for Blood Bank 200 Bag Capacity**
Version no. :		1.0
Date:		10/1/2014
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Refrigerators
GMDN code		CT1897
GENERAL		
1	USE	
1	**Clinical purpose**	A refrigerator for storing whole blood or red cell packs in a blood bank. A refrigerator for storing various reagents and /or patient samples.
TECHNICAL		
2	TECHNICAL CHARACTERISTICS	

2	**Technical characteristics (specific to this type of device)**	Compression type refrigerator that uses CFC free refrigerant gas. **Construction:** Internal: Stainless steel (min. 22g) (S.S. V2 A- 1.4301) External: Solid outer Corrosion Resistant (at least 1mm thickness), CFC free insulation Drawers: Roll out type, Stainless steel scratch resistant material, perforated on the bottom for perfect and homogeneous distribution of cold air. The separators, if provided in the drawers, should be such that blood bags are held in a vertical position with the lable side visible. Door: Glass door, Automatic closing of the front door below opening angle of 90 deg C and opening angle limited to 110 deg C, Insulation and gasket should be silicon. Polyurethane insulation should be minimum 80mm thickness. Door opening audio and visual display alarm. **Temperature Range:** 2 deg C to 6 deg C and adjustable with setting accuracy of ±0.1 deg C with set temperature of 4 deg C. User parameter settings: set point, high alarm point, low alarm point, buzzer off time, C/F temperature choice. **Minimum Compressor Starting Voltage:** 22% below nominal voltage **Internal Temperature Control:** Electronic temperature control, range +2 deg C to +6 deg C with setting accuracy of ±1 deg C whatever the load, Fan air cooling. **External Ambient Temperature:** Performs in an ambient temperature of +10 deg C to +40 deg C. **Hold over time:** A full load of blood packs at +4 deg C (±1 deg C) takes at least 30 minutes to rise to above +6 deg C. Internal temperature hold over time in case of power failure should be at least 1.5 hrs. **Cooling Down Time:** A full load of plasma packs at +25 deg C takes a maximum of 13 hrs for all the packs to reach below +6 deg C **Temperature Monitoring:** Digital temperature (LED) display with 0.1 deg C graduation, Temperature recording device, Microprocessor control for operation with integrated audio visual temperature alarm function with digital monitoring display. Independent safety thermostat to avoid negative temperatures. Atleast 2 temperatures sensors: Sensor for temperature monitoring shown on front display, sensor for managing use of compressor. **Temperature recording device:** Visual and audible alarm system indicating unsafe temperatures. Battery backup for alarm system indicating unsafe temperatures. Seven days graphic temperature recorder with range of -10 deg C to +20 deg C with supply of free charts for a period of one year. Ideal compressor running time of 27% at room temperature. Door locks should be available. Audio and visual alarm for variation in temperature, Interior lightening, Auto defrosting.
2	**Capacity**	As required by the blood bank (200 plasma bags of 350/450 mL each)
2	**Settings**	Manual
2	**User's interface**	Manual

3	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3	**Dimensions (metric)**	NA
3	**Weight (lbs, kg)**	NA
3	**Configuration**	NA
3	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
4	**heat dissipation**	NA
4	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4	**Power Requirements**	input voltage 220/240V 50Hz
4	**Battery operated**	NA
4	**Tolerance (to variations, shutdowns)**	NA
4	**Protection**	A line voltage corrector of appropriate rating will form part of standard configuration.
5	**Power consumption**	NA
5	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.

6	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7	**Product certifications**	European CE or US FDA certified
7	**Quality certifications**	ISO 13485 certified
7	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
8	TRAINING AND INSTALLATION	
8	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8	**Requirements for sign-off**	NA
8	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY AND MAINTENANCE	
9	**Warranty**	2 years
9	**Maintenance tasks**	3 years CMC
9	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.

10	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	NA
11	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**		
	15	**Blood Bank Refrigerator/ Serology Refrigerated 400 bags capacity for B.C.S.U-Blood Collection and Separation Units**
Version no. :		1.0
Date:		10/1/2014
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Refrigerators
GMDN code		CT1897
GENERAL		
1	USE	
1	**Clinical purpose**	A refrigerator for storing whole blood or red cell packs in a blood bank. A refrigerator for storing various reagents and /or patient samples.
TECHNICAL		
2	TECHNICAL CHARACTERISTICS	

2	**Technical characteristics (specific to this type of device)**	Compression type refrigerator that uses CFC free refrigerant gas. **Construction:** Internal: Stainless steel (min. 22g) (S.S. V2 A- 1.4301) External: Solid outer Corrosion Resistant (at least 1mm thickness), CFC free insulation Drawers: Roll out type, Stainless steel scratch resistant material, perforated on the bottom for perfect and homogeneous distribution of cold air. The separators, if provided in the drawers, should be such that blood bags are held in a vertical position with the lable side visible. Door: Glass door, Automatic closing of the front door below opening angle of 90 deg C and opening angle limited to 110 deg C, Insulation and gasket should be silicon. Polyurethane insulation should be minimum 80mm thickness. Door opening audio and visual display alarm. **Temperature Range:** 2 deg C to 6 deg C and adjustable with setting accuracy of ±0.1 deg C with set temperature of 4 deg C. User parameter settings: set point, high alarm point, low alarm point, buzzer off time, C/F temperature choice. **Minimum Compressor Starting Voltage:** 22% below nominal voltage **Internal Temperature Control:** Electronic temperature control, range +2 deg C to +6 deg C with setting accuracy of ±1 deg C whatever the load, Fan air cooling. **External Ambient Temperature:** Performs in an ambient temperature of +10 deg C to +40 deg C. **Hold over time:** A full load of blood packs at +4 deg C (±1 deg C) takes at least 30 minutes to rise to above +6 deg C. Internal temperature hold over time in case of power failure should be at least 1.5 hrs. **Cooling Down Time:** A full load of plasma packs at +25 deg C takes a maximum of 13 hrs for all the packs to reach below +6 deg C **Temperature Monitoring:** Digital temperature (LED) display with 0.1 deg C graduation, Temperature recording device, Microprocessor control for operation with integrated audio visual temperature alarm function with digital monitoring display. Independent safety thermostat to avoid negative temperatures. Atleast 2 temperatures sensors: Sensor for temperature monitoring shown on front display, sensor for managing use of compressor. **Temperature recording device:** Visual and audible alarm system indicating unsafe temperatures. Battery backup for alarm system indicating unsafe temperatures. Seven days graphic temperature recorder with range of -10 deg C to +20 deg C with supply of free charts for a period of one year. Ideal compressor running time of 27% at room temperature. Door locks should be available. Audio and visual alarm for variation in temperature, Interior lightening, Auto defrosting.
2	**Capacity**	As required by the blood bank (400 plasma bags of 350/450 mL each)
2	**Settings**	Manual
2	**User's interface**	Manual
3	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	

3	**Dimensions (metric)**	NA
3	**Weight (lbs, kg)**	NA
3	**Configuration**	NA
3	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
4	**heat dissipation**	NA
4	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4	**Power Requirements**	input voltage 220/240V 50Hz
4	**Battery operated**	NA
4	**Tolerance (to variations, shutdowns)**	NA
4	**Protection**	A line voltage corrector of appropriate rating will form part of standard configuration.
5	**Power consumption**	NA
5	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7	**Product certifications**	European CE or US FDA certified
7	**Quality certifications**	ISO 13485 certified

7	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
8	TRAINING AND INSTALLATION	
8	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8	**Requirements for sign-off**	NA
8	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY AND MAINTENANCE	
9	**Warranty**	2 years
9	**Maintenance tasks**	3 years CMC
9	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA

11	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
	16 Elisa Reader and Washer
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	NA
GMDN code	NA

GENERAL		
1	USE	
1.1	**Clinical purpose**	The system should be capable to wash flat, round and V bottom plates and strips.

TECHNICAL	
2	TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	**(A) Washer:** The system should be fully automated and easy to operate with 8 way mani fold. (1) The system should be capable to wash flat, round and V bottom plates and strips. (2)The should have large display along with more than 40-50 program storage facility. (3) The system should be having automatic calibration facility like well depth, well detection and last row detection. (4) The system should have warning facility for low liquid, vacuum and pressure. (5) Should have specially designed peristaltic pump to dispense 300-400uL in each well. (6) Aspiration of should be contamination through diagram pump while dispensing to prevent overflow residual volume after washing should be < 2 uL. (7) Should be supplied with waste bottle wash bottle and rinse bottle of capacity 2 liter with tubing's. (8) Would have option for washing cycles like long wash, shot wash rinsing and priming. (9) Should be supplied with plastic cover and optional accessories like extra wash bottle. (10) Cross wise aspiration, over flow washing, bottom washing. (11) Automatic manifold detection. (12) 8x12 channel manifold. (13) Equipment should be un-pressurized, capable of using any bottle or container. (14) Volume of wash liquid dispensed. (15) 50 to 3000 uL with 50 uL increment. (16) Suitable for U, V & flat bottom micro plate etc. (17) Residual volume per well < 2 uL. (18) System should be FDA approved/European CE certified. (19) Manufacturer should be ISO 13485 certified. (20) Company should have local based engineer.

		(B) Microplate Reader: 1)Fully Automatic Elisa Plate Reader. 2) Dichromatic optics with six wavelengths. 3) Should have LED lamp with lamp saver feature. 4) Parallel and serial port for External Printer. 5) Printout of the full plate in matrix format. 6) Microprocessor should be Z80a or Z180. 7) Should read Elisa Plate Horizontally A to H & Vertically 1 to 12. 8) Multiple cavity hard coat interference, filters with 10nm half band pass. 9) Photometric Accuracy should be ±1% or better (NIST) 10) Linear measurement range -0.20 to 3.0 absorbance unit./ 11) Stability drift of no more than. 005A in 8 hours. 12) Non volatile memory approximate 36 test with curve ‘s 13) System should be FDA approved/European CE certified. 14) Manufacturer should be ISO 13485 certified. Demonstarion kits for HIV, HCV, HBV should be provided along with the equipment.
2.2	**Capacity**	NA
2.3	**Settings**	Manual
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220/240V, 50Hz
4.2	**Battery operated**	NA

4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	Compatible UPS, to complete the ongoing procedure, with a backup supply for at least half an hour, should be supplied along with.
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)	
17.	**Refrigerated Centrifuge**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Centrifuges and associated devices
GMDN code	CT956

GENERAL		
1	USE	
1.1	**Clinical purpose**	For separation of blood components like packed cells, platelet rich plasma, platelet concentrate, plasma.

TECHNICAL	
2	TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	Refrigerant Centrifuge with CFC free refrigerant. **Construction:** Microprocessor controlled system to make operation automatic. Programmable memory: Memory with tamper proof facility. Stainless steel chamber: Easy to clean, corrosion resistant with provision of both drain and condensed water collection container. Removable plastic cups to hold single/double/triple/quadruple blood bags with partition in every bucket. Insert with hook adapter to spin buffy coat or small volume of blood and balancing weights for inserts. Equipped with automatic lid lock. Speed variation: Microprocessor controlled rotor speed to within 10 rpm of set value. Acceleration and deceleration profiles shall be available. Microprocessor controlled rotor temperature within 1 deg C of set temperature regardless of the centrifuge speed. Programmable time: 0-99 minutes with minimum resolution of 1 minute. Digital display of temperature, speed and time. Minimum no. of 3 digit resolution. Motor imbalance detection: Automatic shut down of centrifuge if rotor load is out of balance with appropriate indicator. Should incorporate alarms for imbalance detection lid interlock, over temperature, rotor over speed. The equipment shall be suitable for operation from 0 to 40 deg C at 90% relative humidity. Electronic circuitry shall be tropicalised for this ambient condition. The equipment shall have lockable castors. Protection of data: In event of power interruption or complete data should remain stored. Should have a provision for external connectivity. It shall have a security lock to prevent unintentional switch off and also unauthorized opening of the equipment. **Electrical specifications:** Automatic Line voltage corrector/Voltage Stabilizer: A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line volatge corrector conforming to IS: 9815 (Pt. I)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under: a) Capacity/rating: 10 KVA, as per requirement of the equipment. b) Input voltage: 140 to 280 volts, 50 cycles. c) output voltage: 220 volts +- 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut off, overload and short circuit protection. d) The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating (15 Amps.) e) Make of the line voltage corrector shall be indicated. **Temperature Range:** From -10 deg C to +40 deg C.
2.2	**Capacity**	Swing bucket blood bank rotor: With metal buckets, 4/6 x 2000mL, wind shielded. Suitable adaptors for 8/12 blood bags of 350mL & 450mL.
2.3	**Settings**	Manual
2.4	**User's interface**	Manual

2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220/240V 50Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.

6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
8	TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Installation on turnkey basis. It is important that company should install and made it operational.
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	1 year
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.

11	NOTES	
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
18.	**Deep Freezer -40^{o}C**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Freezers
GMDN code	CT1898

GENERAL		
1	USE	
1.1	**Clinical purpose**	To freeze and store plasma.

TECHNICAL	
2	TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	Compression freezer with CFC free refrigerant. **Construction:** Internal: Stainless steel (min. 22g) (S.S. V2 A- 1.4301) External: Solid outer Corrosion Resistant (at least 1mm thickness), CFC free insulation Design: Upright Type Door: Solid door, Automatic closing of the front door below opening angle of 90 deg C and opening angle limited to 110 deg C. Insulation and gasket should be silicon, Drawers, Heating device on frame to avoid condensation **Minimum Compressor Starting Voltage:** 22% below nominal voltage **Internal Temperature Control:** Electronic temperature control, Operating temperature reachable lowest up to -45 deg C with setting accuracy of ±1 deg C whatever the load, Fan air cooling, Automatic defrost within safe temperature range, Casing & door should have insulation panel with polyurethane foam > 80mm thickness. **Refrigeration:** Heavy duty hermatically sealed compressor air cooled cascaded refrigeration system, maintains inner temperature below -40 deg C, Option for duct from equipment to connect to common main duct to throw hot air out of the room, Refrigerant CFC free/ green gas, optional: Access port for CO_2 backup system for refrigeration. **External Ambient Temperature:** Performs in an ambient temperature of +10 deg C to +40 deg C **Hold over time:** 2 hrs ambient temperature. **Cooling Down Time:** A full load of plasma packs at +25 deg C takes a maximum of 5 hrs for all the packs to reach below -5 deg C, A full load of plasma packs at +25 deg C takes a maximum of 30 hrs for all the packs to reach below -20 deg C **Temperature Monitoring:** Digital temperature (LED) display with 0.1 deg C graduation, Temperature recording device, Microprocessor control for operation with integrated audio visual temperature alarm function with digital monitoring display. There should be a method to check alarm system, Seven days inkless graphic temperature recorder with range of 0 deg C to -50 deg C with supply of free charts for a period of warranty, Battery backup for alarm and temperature recording device, Mounted on Lockable Castor wheels, Alarm history: Temperature maximum and minimum, average temperature during alarm period, time of duration of alarm, Desirable: Noise factor should not exceed 60 decibels. Should have compressor running time< 60 to 70%.
2.2	**Capacity**	As required by the blood bank (e.g. 200/400/600/900 plasma bags of 200 mL each)
2.3	**Settings**	Manual
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in

3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220/240V 50Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified

7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA

11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
19.	**Deep Freezer -80^{o}C**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Freezers
GMDN code	CT1898

GENERAL		
1	USE	
1.1	**Clinical purpose**	To freeze and store plasma.

TECHNICAL	
2	TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	Compression freezer with CFC free refrigerant. **Construction:** Internal: Stainless steel (min. 22g) (S.S. V2 A- 1.4301) External: Solid outer Corrosion Resistant (at least 1mm thickness), CFC free insulation Design: Upright Type Door: Solid door, Automatic closing of the front door below opening angle of 90 deg C and opening angle limited to 110 deg C. Insulation and gasket should be silicon, Drawers, Heating device on frame to avoid condensation **Minimum Compressor Starting Voltage:** 22% below nominal voltage **Internal Temperature Control:** Electronic temperature control, Operating temperature reachable lowest up to -86 deg C with setting accuracy of ±1 deg C whatever the load, Fan air cooling, Automatic defrost within safe temperature range, Casing & door should have insulation panel with polyurethane foam > 80mm thickness. **Refrigeration:** Heavy duty hermatically sealed compressor air cooled cascaded refrigeration system, maintains inner temperature below -80 deg C, Option for duct from equipment to connect to common main duct to throw hot air out of the room, Refrigerant CFC free/ green gas, optional: Access port for CO_2 backup system for refrigeration. **External Ambient Temperature:** Performs in an ambient temperature of +10 deg C to +40 deg C **Hold over time:** 2 hrs ambient temperature. **Cooling Down Time:** A full load of plasma packs at +25 deg C takes a maximum of 5 hrs for all the packs to reach below -5 deg C, A full load of plasma packs at +25 deg C takes a maximum of 30 hrs for all the packs to reach below -20 deg C **Temperature Monitoring:** Digital temperature (LED) display with 0.1 deg C graduation, Temperature recording device, Microprocessor control for operation with integrated audio visual temperature alarm function with digital monitoring display. There should be a method to check alarm system, Seven days inkless graphic temperature recorder with range of 0 deg C to -50 deg C with data logger, with supply of free charts for a period of warranty, Battery backup for alarm and temperature recording device, Mounted on Lockable Castor wheels, Alarm history: Temperature maximum and minimum, average temperature during alarm period, time of duration of alarm, Desirable: Noise factor should not exceed 60 decibels. Should have compressor running time< 60 to 70%.
2.2	**Capacity**	As required by the blood bank (e.g. 200/400/600/900 plasma bags of 200 mL each)
2.3	**Settings**	Manual
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	

3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220/240V 50Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified

7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA

11.2	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
136.	**Platelet Incubator & Platelet Agitator**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	NA
GMDN code	NA

GENERAL		
1	USE	
1.1	**Clinical purpose**	To continuously agitate platelet concentartes in an incubator in an even suspension ina plasma bag.

TECHNICAL	
2	TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	Flatbed agitator fitted inside a temperature-controlled incubator operating with CFC free refrigerant gas and insulation material. **Construction:** **A. Platelet Incubator:** Should have the provision to store the agitator. Should have a single transparent outer door for clear visibility. Should be able to maintain a temperature of 22+2 deg C, Set temperature of 22 deg C. Should have a digital temperature indicator. Seven day inkless chart recorder with battery backup for minimum of 2 hours for continuous operation during power failure. Single digital temperature sensor for both recording and controlling. Should have audible visual high/low alarm for temperature control, battery on/low, sensor failure, agitator off, power failure, compressor and system. Should have forced air circulation method for the uniformity of the temperature at all sides of the incubator. Chamber mounted electrical outlet for agitator should be available. **B. Platelet Agitator: Internal:** Stainless steel (minimum 304 grade) External: Corrosion resistance, atleast 1mm thickness Capacity: Designed to hold random platelet packs or aphaeresis platelet packs or a mixture of both types (minimum 48 random platelet concentrate packs), Transparent door Design of shelves: Shelves are made of non slip, corrosion resistant material, Coated with bacteria resistant material, perforated to ensure air circulation and with sufficient clearence to minimize noise. Gentle side to side agitation at 3.6-4cm side to side, 60-70 strokes/minute. Heavy duty ball bearing gear motor for noiseless and continuous operation for 24 hrs a day throughout the year. Motor with internal fan. **Refrigeration:** Non CFC air cooled refrigeration. **Temperature:** 7days chart recorder with free charts till one year. Temperature controller with sensor.
2.2	**Capacity**	Designed to hold random platelet packs or aphaeresis platelet packs or a mixture of both types (minimum 48 random platelet concentrate packs), As per requirements (24/48/96 bags)
2.3	**Settings**	Manual
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA

4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220/240V 50Hz
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
7.4	**Safety features**	Audio alarm for temperature fluctuation, Auto stop for agitation when the door is open, Power failure alarm, Push buttons switch with pause function for temporary stoppage of the motion.
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)	
21.	**Laminar Airflow Bench (BioSafety Cabinet)**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Laminar airflow units
GMDN code	CT361

GENERAL		
1	USE	
1.1	**Clinical purpose**	

TECHNICAL	
2	TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	Floor model, Horizontal flow, well lighted, work surface, low vobration and noise, easy to manoevredue to castor wheel provision. Over all diamensions of work space of approximately 1200mm X 600mm X 600mm. **Construction:** Cabinet: Stainless steel sheet of 20 SWG lining. Front panels: Removable transparent sratch resistant sheet of approximately 6 mm thickness. Side panels: Fixed transparent sratch resistant sheet of approximately 6 mm thickness. Work Table: Stainless steel sheet of 20 SWG lining. Pre-Filters: Filteration efficiency of 98% for all types of particles of sizes 8 micron and larger. HEPA filters (fine filters): Filteration efficiency of 99.999% for all types of particles of sizes 0.3 micron and larger. Housed in a frame with leak proof gaskets. Motor Blower: Dynamically balanced and specially constructed to suit low noise and vibration with adjustable speed. Motor shall conform to ISS or any international specifications. Air Velocity: Should not be more than 100 from over the work area. Lighting: Flourescent tube lights with diffuser acrylic to get 120decalux on work surface, Ultra-violet light source shall be provided. Manometer: Should be provided with appropriate manometer to measure the air pressure. LCD Display: Should indicate Exhaust air flow, Laminar flow air velocity, cabinet temperature, Fans elapsed hour meter, HEPA filters last change date. Visual and Buzzer alarm message: Low exhaust flow, low down flow air velocity, impulsion and exhaust fans malfunction, front window not in right position.
2.2	**Capacity**	NA
2.3	**Settings**	Manual
2.4	**User's Interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Diamensions**	1200mm X 600mm X 600mm
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	

4.1	**Power Requirements**	input voltage 220/240V 50Hz, single phase. The equipment shall be provided with both 5 Amp and 15 Amp plug units inside the cabinet.
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	On line voltage corrector of appropriate rating as per standard configuration.
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Installation, commisioning and trial run will be the responsibility of the supplier.
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	1 year
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	The firm shall positively submit printed illustrated technical literature/leaflet including the model quoted by them. If quoted model is modified version of their any standard model that also be indicated in the offer.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
8.1	User manual in English		
8.2	Service manual in English		
8.3	List of important spare parts and accessories with their part number and costing		
8.4	Certificate of Calibration and inspection from the factory		
8.5	Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job descriptin of the hospital technician and company service engineer should be clearly spelt out.		
8.6	List of Equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.		

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
22.	**Plasma Thawing Bath**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Baths and associated devices
GMDN code	CT440

GENERAL		
1	USE	
1.1	**Clinical purpose**	Bath is designed to safely, quickly and optimally and reliably thaw fresh frozen plasma (FFP) and cryoprecipitate for the recovery of coagulation factors and cryoprecipitated antihemophilic factor (AHF). For thawing of plasma and cryoprecipitate at required temperatures.

TECHNICAL		
2	TECHNICAL CHARACTERISTICS	
2.1	**Technical characteristics (specific to this type of device)**	**Construction:** Table top with top opening. Having a deep thawing chamber with a stirrer and with water maintained at +37 deg C with pumping mechanism and inline heating system to ensure uniform thawing. Quick thawing (<20 minutes). Should be able to thaw 4/8 plasma bags (FFP/ cryoprecipitate / Aphaeresis or plasma bags of any size). Should be water bath based system operating at a preset and precise temperature of 37 deg C ±0.2 deg C. Should have two separate basket assemblies with built-in fingers for securely holding the plasma bags of all sizes. Tray with individual compartment to ensure that ports of bags may be kept above water level during the procedure. Should give an alarm when the plasma bags are thawed. Provision for programmable time setting for length of thawing. Should have digital timer clearly displaying the programmed set time or remaining cycle in minutes. Should have audio visual over temperature alarm system. Should have a system to drain the chamber easily. Should be supplied with a cover to keep the unit covered when not in use. Simple to use and easy to read LED display. Drain line with shut-off valve can be connected to existing plumbing. Tray: Removable type stainless steel trays with partitions for holding plasma bags.
2.2	**Capacity**	Capacity of minimum 10 to 15 plasma bags with rack holders
2.3	**Settings**	Manual
2.4	**User's interface**	Manual

2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 220/240V 50Hz, single phase.
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Reusable wrap bag - 8 numbers, frozen plasma bag holder, compression rack holder, reference thermometer.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.

6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 years
5	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.

11	NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

MEDICAL DEVICE SPECIFICATION **(Including Information on the following where relevant/appropriate, but not limited to)**	
23.	**Refrigerated Water Bath (Cryobath)**
Version no. :	1.0
Date:	10/1/2014
Done by : (name / institution)	HCT/ NHSRC

NAME AND CODING	
GMDN name	Water baths
GMDN code	CT521

GENERAL		
1	USE	
1.1	**Clinical purpose**	For uniform thawing of plasma bags.

TECHNICAL		
2	TECHNICAL CHARACTERISTICS	
2.1	**Technical characteristics (specific to this type of device)**	For uniform thawing of plasma bags at preset temperature of $4^{o}C \pm 0.2^{o}C$. **Construction:** For uniform thawing of plasma bags at preset temperature of 4 deg C±0.2 deg C. High capacity pump to facilitate optimum and uniform thawing of plasma. System to prevent contamination of individual ports during thawing. Microprocessor based digital controller to precise monitoring and controlling of temperatures at 4 deg C±0.2 deg C. Stainless steel tank of 22 guage and stainless steel lid of at least 20 gauge. Drain line with shut off valve can be connected to existing plumbing. Mounted on lockable castor wheels. Temperature sensing method: Sealed sensor dipped directly in the water. Power Consumption: Maximum 1600 W Operating Temperatures: 3.5 deg C - 4.5 deg C Programmable temp. range: 3 deg C - 50 deg C Display resolution: 0.1 deg C Time taken: Time taken for one process should not be more than 2 hours for plasma bags store at -40 deg C. Tray: Stainless steel, removable tray of individual compartments for holding plasma bags.
2.2	**Capacity**	10-12 bags per run or per one cycle
2.3	**Settings**	Manual
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	Built in
3	PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	Should be less than 850mm X 500mm X 500 mm (±10%)
3.2	**Weight (lbs, kg)**	Less than 70 Kg
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise factor should not exceed 60 decibels.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	NA
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)	
4.1	**Power Requirements**	input voltage 230 + 10%V, 50Hz, 15 Amp single phase AC
4.2	**Battery operated**	NA

4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately.
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**Additional Requirements**	All equipments should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished.
6.3	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant.
7	STANDARDS AND SAFETY	
7.1	**Product certifications**	European CE or US FDA certified
7.2	**Quality certifications**	ISO 13485 certified
7.3	**Electrical Safety**	Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
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) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
9	WARRANTY 2 YEARSAND MAINTENANCE	
9.1	**Warranty**	2 years
9.2	**Maintenance tasks**	3 years CMC
9.3	**Service contract clauses, including prices**	**Downtime:** 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
10	DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be declared

MPPHSCL/15-16/BB/BCSU/Specifications

LAST PAGE _OF SPECIFICATIONS i.e. Annexure B Page no 152 –To be read with the Tender for Blood Bank and Blood Collection Separation Unit dated 11.05.2015