

**ATTACHMENT 4B
 FRAMEWORK AGREEMENT SPECIFICATION
 BLOOD COLLECTION DEVICES, BLOOD LANCETS AND TOURNIQUET**

1. Introduction

- 1.1. The Framework Agreement is for the supply of blood collection devices and blood lancets which includes blood collection sets, Initial Specimen Diversion Device (ISDD), needles, blood gas syringes, finger and heel lancets, single use, reusable tourniquets, and vein locator.
- 1.2. The Framework Agreement is for the following Lots.

Lot Number	Lot Title
1	Blood Collection Devices
2	Blood Lancets
3	Tourniquet
4	Vein Locator

1.3. Full technical specifications of the product lines awarded to the Framework Agreement (each a **“Technical Specification”** and together the **“Technical Specifications”**) must be made available to NHS Supply Chain on request during the term of the Framework Agreement.

1.3.1. Applicants must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement.

1.3.2. If changes to the Technical Specification of any product line awarded to the Framework Agreement mean that the product line no longer meets the minimum requirements outlined in the Specification, NHS Supply Chain reserves the right to exclude that product line from the Framework Agreement.

1.3.3. NHS Supply Chain reserves the right to request evidence of compliance with the Specification throughout the term of the Framework Agreement.

1.4. This Framework Agreement Specification makes reference to a number of standards and legislation. The list of standards and legislation is not intended to be exhaustive and any relevant standards and legislation which applies to the Framework Agreement (even if not stated) must be complied with by Applicants

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 1 of 18

(together with those listed in this Framework Agreement Specification the “**Standards and Legislation**”).

- 1.5. Product lines must comply with the Standards and Legislation (as amended, extended, or re-enacted from time to time).
- 1.6. Evidence of compliance to the Standards and Legislation must be provided by Applicants awarded to the Framework Agreement (“**Suppliers**”) to NHS Supply Chain on request during the term of the Framework Agreement; in the event that sufficient evidence is not provided by Suppliers NHS Supply Chain reserves the right to suspend product lines until such evidence is provided by Suppliers.

2. Criteria applicable across all product lines

2.1. Standards and Legislation

STANDARD AND LEGISLATION
Where products are classed as Medical Devices as per the definition under Medical Devices Regulation 2017/745 the following will apply:
Medical Devices Directive 93/42/EEC (as amended) All products must have their CE or UKCA marking evident on the product and/or packaging.
And / Or
Medical Devices Regulation 2017/745 (as amended) All products must have their CE or UKCA marking evident on the product and/or packaging.
And / Or
ISO/CD 15223-1 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.
BS EN ISO 20417:2021 (previously BS EN 1041:2008 +A1:2013.) Medical devices. Information to be supplied by the manufacturer.
BS EN ISO 15223-1:2016 or BS EN ISO 15223-1:2021 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied or medical devices Symbols to be used with information to be supplied by the manufacturer – General requirements.
BS EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 2 of 18

BS EN ISO 80369-7:2021 (previously BS EN ISO 80369-7:2017)

Small-bore connectors for liquids and gases in healthcare applications.
Connectors for intravascular or hypodermic applications

BS EN ISO 23908:2013

Sharps injury protection. Requirements and test methods. Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.

Where products are sterile, they must comply with either applicable standard below or equivalent international standard to designate device as sterile.

BS EN 556-1-2001

Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.

BS EN 556-2-2015

Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for aseptically processed medical devices.

Where a product is sterilised an applicable validated sterilisation and routine control process must be applied, for example:

BS EN ISO 14937:2009

Sterilization of health care Sterilization of health care products.

BS EN ISO 11135:2014+A1:2019

Sterilization of health-care products. Ethylene oxide

BS EN ISO 11137-4:2015+A2:2019. Sterilization of healthcare products. Radiation Requirements for the development, validation, and routine control of a sterilization process for medical devices

BS EN ISO 17665-1:2006

Sterilization of health care products. Moist heat. Requirements for the development, validation, and routine control of a sterilization process for medical devices

2.2. On request applicants must provide NHS Supply Chain with Safety Data Sheets (SDS) for all products that fall under REACH (Registration, Evaluation, Authorisation, and restriction of Chemicals) 2007 –more specifically, an SDS must be provided if a substance or a mixture supplied is classified as hazardous under the CLP Regulation (EC) No 1272/2008.

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 3 of 18

- 2.3. If a product line contains phthalates this must be indicated on the packaging of that product line in accordance with Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC).
- 2.4. If a product contains DEHP must be stated on the individual product packaging or IFU (instructions for use) and / or made available to NHS Supply Chain or end user on request.
- 2.5. All product lines and packaging should be latex free where possible. If a product line or any packaging contains latex this must be labelled on the product line or packaging (as applicable) to inform the user.
- 2.6. All product line(s) excluding Blood collection tubes must be supplied with a minimum 1-year shelf life, Min 6 months shelf life is required for the blood collection tubes.
- 2.7. All product lines must be delivered free of charge to a location as directed by either NHS Supply Chain or the customer.
- 2.8. IFUs must be written in English or pictograms and included on the individual product packaging and/or within the UOI and/or made available to NHS Supply Chain or end user on request.
- 2.9. Any cautions / warnings / contraindications to use must be provided in IFU.
- 2.10. Must state details strictly necessary to identify the device for the user on the individual product packaging.
- 2.11. Lot number and expiry date must be stated on the individual product packaging.
- 2.12. For ordering purposes an identifier for example reference / manufacturing product code (MPC) must be stated on the individual product packaging and/or unit of issue packaging.
- 2.13. Product must be robust enough to resist breakage when used as directed by manufacturer.
- 2.14. Where applicable, products must be supplied sterile and individually wrapped.

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 4 of 18

- 2.15. Individual packaging must be of durable construction preventing product being pushed through, tampering and must not tear or rip apart during transportation and storage, to avoid damage to the product and / or breaches of product sterility and to reduce risk of plastic packaging being a foreign body when device being used.
- 2.16. Instructions for storage and disposal of device must be stated on the individual product packaging and/or IFU and / or made available to NHS Supply Chain or end user on request.
- 2.17. Where applicable, the product packaging must include a non-adherent tab which allows product packaging to be opened at one end maintaining sterility.
- 2.18. Where applicable, the word single use and / or symbol must be depicted on the individual product packaging to inform the user of the products single use status in line with labelling (ISO 15223).
- 2.19. Where applicable, products that are sterile, the transparent side of the individual packaging must allow visualisation of the contents.
- 2.20. Conditionality to MRI/CT must be indicated on product packaging or IFU to inform the user or be made available upon request.
- 2.21. Where the product contains tubing, the packaging must be designed to minimise the risk of kinking of tubing while in storage.
- 2.22. Information of the product constituent's raw material/s must be made available to NHS Supply Chain or end user on request to support with customer recycling requirements.
- 2.23. Country of origin must be made available to NHS Supply Chain or end user on request.
- 2.24. Weight of product must be made available to NHS Supply Chain or end user on request to provide trust with weight waste information.
- 2.25. Where applicable, must be stated if external product packaging is made of recyclable material and /or recyclable.

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 5 of 18

- 2.26. Training and education on the usage, maintenance, testing and calibration of the devices must be provided on request and in accordance with trust requirements through mutual agreement.
- 2.27. Changes to packages and labels must be sent to NHS Supply Chain for pre-approval to ensure it meets standard clinical practice.
- 2.28. All products where applicable must be registered with the MHRA.
- 2.29. During the term of the Framework Agreement Applicants must make NHS Supply Chain aware of any awarded product line that is classed by the MHRA as a Medicinal Product.
3. **Lot 1 – Blood Collection Devices** - This Lot is for the supply of blood collection devices which includes blood collection needles, Initial Specimen Diversion Device (ISDD), blood collection sets, blood gas syringes, and blood collection sampling tubes that can be but “not limited to” include additive concentrations.
- 3.1. All products must be single use and must be stated on this on the individual product packaging.
- 3.2. Paper backed packaging must resist tears and punctures.
- 3.3. Where blister pack packaging is used it must include a non-adhesive tab which allows product to be opened at one end maintaining sterility.
- 3.4. Packaging must permit opening in an aseptic manner that allows for sterile items to be removed or transferred to the sterile field.
- 3.5. Plastic / see through side of blister pack packaging must not tear when the packaging is opened.
- 3.6. **Blood Collection Safety Needles** – A sterile needle used for drawing blood from a patient in accordance with safer sharps regulations (Health and Safety - Sharp Instruments in Healthcare Regulations 2013).
- 3.6.1. Blood collection needles can include needles with protection devices (safety shields to prevent needle stick injuries) and holders.
- 3.6.2. Protection devices must meet the requirements of EU Directive 2010/32/EU.

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 6 of 18

3.6.3. Product must be supplied with or have access to instructions or pictorial illustration to activate safety mechanism.

3.6.4. The safety mechanisms must not be reversible once activated.

3.6.5. The safety mechanism must not interfere with line of sight.

3.6.6. Must be supplied sterile.

3.7. **Blood Collection Needles** – A sterile needle used for drawing blood.

3.7.1. Blood collection needles can include needles with protection devices (safety shields to prevent needle stick injuries) and holders.

3.7.2. Product must be supplied with or have access to instructions or pictorial illustration.

3.7.3. Must be supplied sterile.

3.8. **Blood Collection Safety Sets** – A collection of devices intended to be used by a healthcare professional, in combination with blood collection sampling tubes for the routine collection of multiple blood specimens from a patient, via one venipuncture, for clinical analyses. It consists of a blood collection needle or venous butterfly/scalp vein needle and additional devices that may include tubing, male/female Luer-lock connectors, clamps, and a blood collection tube holder. Blood access is directly through the vein with the needle. This is a single-use device.

3.8.1. Must meet all the requirements in paragraph 3.1-3.5 and the following additions. Sets must contain as a minimum:

3.8.1.1. stainless steel needle

3.8.1.2. flexible tubing

3.8.1.3. Safety Mechanism

3.8.2. Product must be supplied with instructions or pictorial illustration to activate safety mechanism.

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 7 of 18

3.9. **Blood Sample tubes** - a sterile glass or plastic tube with a place for the identification, labelling and/or tracking of blood samples including a closure. These can be but "not limited to" be supplied already evacuated or can be evacuated to create a vacuum inside the tube facilitating the drawing of a predetermined volume of liquid – including but not limited to;

3.9.1. Blood sample tube with sodium citrate for coagulation;

3.9.2. Blood sample tube for capillary collection;

3.9.3. Blood sample tube with EDTA (Ethylenediaminetetraacetic acid);

3.9.4. Blood sample tube with glucose fluoride oxalate/potassium oxalate;

3.9.5. Blood sample tube for blood bank;

3.9.6. Blood sample tube with plasma heparin;

3.9.7. Blood sample tube for serum separation with and without gel;

3.9.8. Blood sample tube (either glass or plastic) for ESR (Erythrocyte Sedimentation Rate).

3.10. **Blood Gas Syringes** – plastic or glass syringes used for blood gas samples, supplied pre-packaged and containing heparin, or able to be heparinised, to prevent coagulation.

3.10.1. Products must comply with BS EN ISO 80369-7: 2021 Small-bore connectors for liquids and gases in healthcare applications.

3.10.2. Volume number and measured graduation lines must be on the product.

3.10.3. Must be able to draw blood syringe with one hand.

3.10.4. Must have preventative mechanism to help prevent the plunger detachment.

3.10.5. Must be heparinised or have ability to be heparinised.

3.10.6. If Un-heparinised mixing requirements / instructions for use must be included with the product on IFU or individual product packaging.

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 8 of 18

3.10.7. Must be plastic or glass in construction.

3.10.8. Must have a syringe covering to prevent contamination of sample, for example with a cap.

3.10.9. Must have luer lock thread or luer slip connection.

3.10.10. Must be supplied sterile.

3.11. **Blood gas syringes with needle** must meet all the requirements in paragraphs 3.1-3.5 and the following additions.

3.11.1. Must have standard or safety needle that is removable.

3.11.2. Plunger must move or syringe fills up when arterial pulsation is detected.

3.11.3. Support Products include:

3.11.3.1. Holders and adaptors for blood culture media.

3.11.3.2. Caps.

3.11.3.3. Blood sample transport box

3.12. **Blood Culture Collection Devices** - This is for the supply of Blood Culture Collection devices which includes an automatic (and passively activated) Initial Specimen Diversion Device (ISDD) with safety devices, may or may not include safety winged needles, blood collection sampling tubes and with connection to an intravascular access device.

3.12.1. Blood Culture Collection devices are designed to increase the safety of routine venepuncture procedures and prevent needle stick injuries.

3.12.2. Blood Culture Collection devices must contain as a minimum:

3.12.2.1. Stainless Steel Needle

3.12.2.2. Sharp-Safety Mechanism

3.12.2.3. Flexible Tubing

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 9 of 18

- 3.12.2.4. Automatic blood diversion device to side line the first flash of blood
- 3.12.3. All products must be single use, and this must be stated on individual product packaging.
- 3.12.4. All products must be sterile.
- 3.12.5. Product must state details strictly necessary to identify the device for the user.
- 3.12.6. Product must have flash chamber to allow visualisation of proper needle to vein placement.
- 3.12.7. Product must have a flash chamber that collects and isolates first flash of blood.
- 3.12.8. Product gauge or length must be stated on the product packaging or IFU.
- 3.12.9. Where blister pack packaging is used it must include a non-adhesive tab, perforation or slit, which allows product to be opened at one end maintaining sterility.
- 3.12.10. Packaging must permit opening in an aseptic manner that allows for sterile items to be removed or transferred to the sterile field.
- 3.12.11. Packaging must have a transparent side to allow visualization of the product.
- 3.12.12. The expiry date and production Lot number must be stated on the individual product packaging.
- 3.12.13. Plastic / see through side of blister pack packaging must not tear when the packaging is opened.
- 3.12.14. Protection devices must meet the requirements of EU Directive 2010/32/EU and safer sharps regulations (Health and Safety - Sharp Instruments in Healthcare Regulations 2013).

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 10 of 18

3.12.15. Product must be supplied with or have access to instructions or pictorial illustration to activate safety mechanism.

3.12.16. The safety mechanisms must not be reversible once activated.

3.12.17. The safety mechanism must not interfere with line of sight.

3.12.18. Must have luer lock thread or luer slip connection.

3.12.19. Associated support products to include but not restricted to; -

3.12.19.1. Holders and collection adaptors caps.

3.13. **Blood Culture Pack or Kit** - This is a collection of devices intended for the collection of blood for culture, can be directly from a venous puncture or from vascular access devices. Products included in this sub-category must meet requirements for relevant specification points raised in the above headers.

3.13.1 This may include but not limited to all the above components in 3.12 and other dedicated devices intended to support the procedure, e.g., sterile drape, tourniquet, swabs, dressings, sterile antiseptic solution containing a combination of 2% Chlorhexidine gluconate in 70% isopropyl alcohol.

3.13.2 Blood culture kits/packs must open in such a way to allow one-ended product opening in adherence to aseptic technique/ANTT principle for example peel pack or perforation.

4. **Lot 2 Blood Lancets** - This Lot includes Lancing devices that are a sterile, hand-held, sharply pointed, mechanical and non-mechanical, scalpel-like instrument intended to be used by a healthcare provider to manually puncture the skin of a patient to obtain a small blood specimen or drain a cyst or boil. This is a single-use device. This lot includes both finger and heel lancets.

4.1. Blood lancets must be able to puncture the epidermis before penetrating the reticular layer safely and effectively enough to produce adequate blood flow for a variety of test.

4.2. A lancing system consists of a lancing device / lancet blade which automates the procedure.

4.3. Lancets must be single use.

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 11 of 18

- 4.4. Product gauge or length of incision must be stated on the product packaging and/or instruction for use.
- 4.5. Instructions for use must be included with the product.
- 4.6. The expiry date and lot number must be stated on the product packaging.
- 4.7. Products must not activate prematurely when prepared using the steps indicated by the manufacturer.
- 4.8. Following activation, the needle must be fully retracted.
- 4.9. Single use safety lancets must penetrate to a depth to expose sufficient blood vessels to provide an adequate blood flow.
- 4.10. Single use safety heel newborn/full term lancets must penetrate to a depth to expose sufficient blood vessels to provide an adequate blood flow.
- 4.11. Blood Lancet blades must be made from medical grade stainless steel.
- 4.12. The incision method of the single use safety heel lancets must be an arc motion/sweeping/pendulum action swinging from side to side.
- 4.13. Single use safety heel premature lancets must incise to a depth of 0.85mm x width 1.75mm
- 4.14. Single use safety heel newborn/ full term lancets must incise to a depth of 1.00mm x width 2.50mm

5. Lot 3 Tourniquet - A band-like device that is applied around an extremity (arm or leg) and connected to a tourniquet unit to apply a controlled pressure to restrict blood circulation and prevent normal blood flow to or from the distal area for use in the procedure of collect blood samples.

5.1. This lot includes:

5.1.1. Band type tourniquets

5.1.2. Quick release button tourniquets

5.1.3. Quick release pull-through tourniquets.

5.1.4. Reusable tourniquets

5.2. All products within this Framework must meet the following requirements:

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 12 of 18

5.2.1. Be clinically clean;

5.2.2. Have a fastening mechanism allowing for single handed release.

5.3. Products within this Framework must not be supplied with hook and loop fastenings.

5.4. **Single use - Band Type Tourniquets** - Band application type tourniquets are elasticated tourniquets used in the procedure of blood sampling for restricting blood flow **for adult and bariatric use**.

5.4.1. All products must meet all of 5.2 plus the following:

5.4.2. Band type tourniquets must have a fastening mechanism that is tuck and loop to provide tourniquet effect, this must be stated / depicted in the instructions provided.

5.4.3. Must be single use.

5.4.4. Each product must dispense individually from the packaging.

5.4.5. Product must be robust enough to resist breakage when tourniquet effect is being applied as directed by manufacturer.

5.4.6. Product design must minimise risk of harm to skin when tourniquet is applied as directed by manufacturer.

5.4.7. Single Band Type for adult use must be within the following sizes, please note if tourniquets are provided on a roll, then these measurements apply to the perforated sections of the roll i.e., the individual tourniquets;

5.4.7.1. Length: minimum of 440mm, to a maximum of 470mm and

5.4.7.2. Width: minimum of 24mm.

5.4.7.3. Product must have a minimum tensile strength of 76N/m², or 0.000076MPa, or 76Pa and evidence of compliance must be provided on request.

5.5. **Single Use Tourniquet - Quick Release Button Fastening**

5.5.1. Products within this Lot include:

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 13 of 18

5.5.1.1. Single button fastening tourniquets; and

5.5.1.2. Multiple buttons fastening tourniquets.

5.5.2. Single button fastening tourniquets are elasticated tourniquets used in the procedure of blood sampling for restricting blood flow and are for adult, bariatric and paediatric use.

5.5.3. All products must meet all of 5.2 plus the following:

5.5.4. Single button fastening tourniquets for adult use must be within the following sizes;

5.5.4.1. Length: minimum of 340mm, to a maximum of 460mm and

5.5.4.2. Width: minimum of 21.6mm, to a maximum of 26.4mm.

5.5.5. Product must have holes placed at varying intervals to allow tourniquet effect to be applied to varying limb sizes.

5.5.6. Must be single use.

5.5.7. For bariatric products a single band solution is required.

5.5.8. Must not disconnect during normal use to maintain a tourniquet effect.

5.5.9. Product must be robust to resist breakage when tourniquet effect is being applied as directed by manufacturer.

5.5.10. Product design must minimise risk of harm to skin when tourniquet is applied as directed by manufacturer.

5.5.11. Fastening methods for the single button fastening tourniquets:

5.5.11.1. Must only have a single button to secure the tourniquet in place; and

5.5.11.2. Must have the ability to allow for single handed release.

5.5.12. Multiple buttons fastening tourniquets are used in the procedure of blood sampling for restricting blood flow.

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 14 of 18

5.5.13. Fastening methods for the multiple buttons fastening tourniquets:

5.5.13.1. Must have a minimum of two buttons to secure the tourniquet in place; and

5.5.13.2. Must have the ability to allow for single handed release.

5.6. **Single Use Tourniquet – Quick Release Pull Through Fastening** - This Lot is for pull through fastening tourniquets **for adult, bariatric and paediatric use.**

5.7. Pull through tightening fastenings are used in the procedure of blood sampling for restricting blood flow.

5.8. All products must meet all of 5.2 plus the following:

5.8.1. Fastening methods for the pull through tourniquets must have one end of the tourniquet pass through itself and tighten through material resistance or one end of the tourniquet must pass through itself and be secured with adhesive.

5.8.2. Must be single use.

5.8.3. Each product must dispense individually from the packaging.

5.8.4. Product must be robust enough to resist breakage when tourniquet effect is being applied as directed by supplier.

5.8.5. Product design must minimise risk of harm to skin when tourniquet is applied as directed by manufacturer.

5.9. **Reusable Tourniquets** - Reusable tourniquets - Elasticated band which are used in the blood sampling procedure to restrict blood flow that can be cleaned / decontaminated and reused at point of care as per local Trust policy **and are for adult, bariatric and paediatric use.**

5.10. All products must meet all of 5.2 plus the following:

5.10.1. Product must be robust enough to resist breakage when tourniquet effect is being applied as directed by supplier.

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 15 of 18

5.10.2. Product design must minimise risk of harm to skin when tourniquet is applied as directed by manufacturer.

5.10.3. Must have quick release mechanism.

5.10.4. Decontamination instructions must be provided with the product.

5.10.5. Instructions on how many times the product can be used and when to dispose of them must be included in instructions for use and must be provided to NHS Supply Chain and/or end user on request.

6. Lot 4 - Vein Locator - An electrically powered device designed to help locate peripheral veins beneath the skin (subcutaneous) for example, infrared (IR) laser-generated light or light-emitting diodes (LED). It is intended to illuminate the position of veins on the skin surface directly above the veins to assist a trained healthcare professional in finding a vein of the right size and position for venepuncture. It may also be known as an IR vein finder, viewer or transilluminator, and may include a small interface screen to cycle through previously stored display settings to help optimize vein display for the patient undergoing examination/treatment.

6.1. Where the device is hand-held, it may also be used with a hands-free option, for example, a clamp or flexible arm kit to support the device to allow user to perform procedure of venepuncture and cannulation.

6.2. Device must indicate depth of visibility, for example 10mm, (and other basic functionalities) to inform the user. This must be made available to the customer or NHS Supply Chain upon request.

6.3. The distance between device and skin surface must be provided to inform the user.

6.4. Where appropriate, the device must depict battery mode and battery power level.

6.5. The image display must depict and provide the user intended visibility of the vein.

6.6. On site training must be made available for end user of the full functionality competency-based user. Training for the full functionality of the product must

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 16 of 18

be included in the costs including mechanical functionality and general operation.

6.7. Training and implementation must be provided on request and in accordance with trust requirements through mutual agreement. This could be for example, providing ongoing support including pre-implementation education, supplier support and implementation guidance, bespoke clinical training, eLearning, and post-implementation support.

6.8. Device must be able to be cleaned to prevent cross contamination and must have available cleaning / decontamination instructions and provide to NHS SC on request.

6.9. When present, batteries must be housed in the product in a secure way to prevent them falling out when product is used as per manufacturer's instructions. This will ensure function of the product is not detrimentally affected.

6.10. Where applicable, battery test results must meet the 'Minimum Average Duration' ("MAD") as specified in International Electrotechnical Commission (IEC) 60086-2:2015 as a minimum. For each delivered batch, the corresponding batch data sheet must be made available to NHS Supply Chain on request.

6.11. Devices must be tested and assessed to account for differences pertaining to population characteristics to reduce biases against medical device users of different genders, ethnicities, or other socio-demographic groups, for example, testing of devices on different skin tones.

6.12. Product Evaluations: - Any product trials/evaluations agreed to take place by both the Provider and the Trust will be at no charge to the Trust. For avoidance of doubt this includes, but is not limited to:

6.12.1. Product and equipment

6.12.2. Delivery charges

6.12.3. Load kit charges

6.12.4. Training and clinical support

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 17 of 18

STANDARDS AND LEGISLATION	TENDER REQUIREMENTS
<p>Medical Devices Directive 93/42/EEC (as amended) All products must have their CE or UKCA marking evident on the product and/or packaging.</p> <p>Or</p> <p>Medical Devices Regulation 2017/745 (as amended) All products must have their CE or UKCA marking evident on the product and/or packaging.</p>	<p><u>Class I</u></p> <ul style="list-style-type: none"> Declaration of conformity to the Medical Devices Directive 93/42/EEC to be provided with your Tender response. <p><u>Class I Sterile, Class I measuring, Class IIa, Class IIb and Class III</u></p> <ul style="list-style-type: none"> CE certificate from a notified body to be provided with your Tender response; and Declaration of conformity to the Medical Devices Directive 93/42/EEC to be provided with your Tender response. <p>Where not Applicable Provide a statement confirming why this Directive does not apply to your product(s) submitted for a product line. You will need to do this for each product line where this Directive is not applicable to your product(s).</p>

Document #: LEGAL TEMP 810-06		
Revision: 16	V16 Final Specification -Blood collections –	Page 18 of 18