FRAMEWORK AGREEMENT SPECIFICATION
BLOOD CULTURE COLLECTION SYSTEMS
INITIAL SPECIMEN DIVERSION DEVICE (ISSD)

1. Introduction

1.1. The Framework Agreement is for the supply of safety blood culture collection systems with initial specimen diversion devices (ISSD) intended for use in acute and community clinical settings.

1.2. 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.

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

1.2.2. 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.

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

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

1.4. Product lines must comply with the Standards and Legislation (as amended, extended or re-enacted from time to time).

1.5. 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. **Or** **Medical Devices Regulation 2017/745 (as amended)** All products must have their CE marking evident on the product and/or packaging. **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. **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 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 EN556-2-2015** 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 series** Sterilization of health care products. Radiation

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. 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).

2.3. All product lines and packaging should be latex free where possible. If a product line or any packaging contains or does not contain latex this must be labelled on the product line or packaging (as applicable) to inform the user.

2.4. If a product contains DEHP must be stated on the individual product packaging or IFU and/or made available to NHS Supply Chain or end user on request.

2.5. All product line(s) must be supplied with a minimum 1 year's shelf life.

2.6. Instructions for use (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. Any cautions / warnings / contraindications to use must be provided in IFU.

2.7. Unit of issue product packaging and/or product packaging must state details strictly necessary to identify the device for the user, where individual product packaging allows for visualisation of product no additional detail will be required on packaging.

2.8. Where a product is single use, 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).

2.9. All sterile products must have a transparent side to allow visualisation of the product through the individual product packaging.

2.10. If MRI compatible it must be stated on the individual product packaging and/or unit of issue packaging.

2.11. Information on 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.

2.12. Information on Country of origin must be made available to NHS Supply Chain or end user on request.

2.13. Information on weight of product must be made available to NHS Supply Chain or end user on request to provide trust with weight waste information.

3. Blood Culture Collection Systems

3.1. This is for the supply of Blood Culture Collection Systems which includes an automatic (and passively activated) Initial Specimen Diversion Device (ISSD) with safety devices, with or without safety winged needles, with or without evacuated blood collection tubes and with connection to an intravascular access device.

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

3.3. Blood Culture Collection Systems must contain as a minimum:
- 3.3.1.1. Stainless Steel Needle
- 3.3.1.2. Sharp-Safety Mechanism
- 3.3.1.3. Flexible Tubing
- 3.3.1.4. Automatic blood diversion device to side line the first flash of blood

3.4. All products must be single use, and this must be stated on individual product packaging.

3.5. All products must be sterile.

3.6. Product must state details strictly necessary to identify the device for the user.

3.7. Product must have flash chamber to allow visualisation of proper needle to vein placement.

3.8. Product must have a flash chamber that collects and isolates first flash of blood.

3.9. Product gauge or length must be stated on the product packaging or IFU.

3.10. 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.

3.11. Packaging must permit opening in an aseptic manner that allows for sterile items to be removed or transferred to the sterile field.

3.12. Packaging must have a transparent side to allow visualization of the product.

3.13. The expiry date and production Lot number must be stated on the individual product packaging.

3.14. Plastic / see through side of blister pack packaging must not tear when the packaging is opened.

3.15. 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).

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

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

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

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

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

3.16.1. Holders and collection adaptors caps.