APPENDIX 3

FRAMEWORK AGREEMENT SPECIFICATION
NEEDLEFREE CONNECTION SYSTEMS AND ASSOCIATED PRODUCTS

1. Introduction

1.1. The Framework Agreement is for the supply of needle free connectors and connection systems/access devices intended to provide direct infusion of fluids or administration of medication to a patient including:

- 1.1.1. Luer activated needle free connectors (including positive, negative, neutral displacement and bi-directional fluid control types) including:
  - 1.1.1.1. Luer lock Connector
  - 1.1.1.2. Bi-directional fluid control
  - 1.1.1.3. Negative displacement
  - 1.1.1.4. Arterial - negative displacement
  - 1.1.1.5. Neutral displacement
  - 1.1.1.6. Arterial - neutral displacement
  - 1.1.1.7. Positive displacement
- 1.1.2. Needlefree extension sets with integrated needlefree connectors.
- 1.1.3. Needlefree accessories including vial access devices, medical use stopcocks, transfer spike and bag spikes.
- 1.1.4. Needlefree disinfection cap
- 1.1.5. Closed Transfer System Device

1.2. The Framework Agreement is for the following Lots

Lot Number	Lot Title
1	Needlefree Connection Systems
2	Needlefree Disinfection Caps
3	Closed System Transfer Devices

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 (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
Medical Devices Directive 93/42/EEC (as amended) All products must have their CE marking evident on the product and/or packaging

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. All products must be supplied sterile unless requested otherwise.

2.5. All products must be compatible with Chlorhexidine swabs and 70% alcohol swabs for disinfection.

2.6. The needlefree product must be visible on one side of the individual packaging.

2.7. The product must include a non-adherent tab which allows product to be opened at one end maintaining sterility.

2.8. All product line(s) must be supplied with a minimum 2 years shelf life.

3. Lot 1 - Needlefree Connection Systems

3.1. Luer activated needlefree connectors must:

3.1.1. Allow repeated access to the intravenous system whilst eliminating the use of needles.

3.1.2. Be activated by a male luer fitting such as a syringe or administration set.

3.1.3. Automatically return to a closed position, sealing the fluid pathway upon removal of a syringe or administration set.

3.1.4. Allow the connection of a syringe to a catheter.

3.1.5. Must be available in at least one of the following configurations;
- 3.1.5.1. Negative fluid displacement;
- 3.1.5.2. Neutral fluid displacement;
- 3.1.5.3. Positive fluid displacement; or
- 3.1.5.4. Bi-directional fluid control.

3.1.6. Accept and remove all standard luer slip and luer lock connections in accordance with **BS EN ISO 80369-7:2017** Small-bore connectors for liquids and gases in healthcare applications. Connectors for intravascular or hypodermic applications.

3.2. Needlefree extension sets must:

3.2.1. Contain a connector that meets all the requirements in section 3.1.

3.2.2. Include an integrated extension set that allows repeated access to the intravenous system whilst eliminating the use of needles.

3.2.3. Be capable of use with the product clamp continuously without the extension tubing being damaged.

3.2.4. Have an integrated extension set made from either Polyethylene, Polyethylene lined PVC, PVC or Polyurethane.

3.3. Needlefree accessories must:

3.3.1. Contain a connector that meets all the requirements in section 3.1

4. Lot 2 - Needlefree Disinfection Caps

4.1. All needlefree disinfection caps must meet the following requirements:

4.1.1. Fit all needlefree connectors

4.1.2. Contain 70% isopropyl alcohol

4.1.3. Be single use

5. Lot 3 – Closed System Transfer Devices

5.1. Closed System Transfer Device (CSTD) Male Luer Connector must:

5.1.1. Provide a mechanically closed system that prohibits the transfer of environmental contaminants into a system and the escape of hazardous drug or vapor concentrations outside the system.

5.1.2. Accept and remove all standard luer lock connections in accordance with **BS EN ISO 80369-7:2017** Small-bore connectors for liquids and gases in healthcare applications. Connectors for intravascular or hypodermic applications.

5.2. Closed System Transfer Device (CSTD) Male Non-Luer Connector must:

5.2.1. Provide a mechanically closed system that prohibits the transfer of environmental contaminants into a system and the escape of hazardous drug or vapor concentrations outside the system.

5.3. Closed System Transfer Device IV Set and Bag Spike must:

5.3.1. Include the integrated CSTD connector

5.4. Closed System Transfer Device Vial Access Device must:

5.4.1. Provide a mechanically closed system that prohibits the transfer of environmental contaminants into a system and the escape of hazardous drug or vapor concentrations outside the system.

STANDARDS AND LEGISLATION	TENDER REQUIREMENTS
Medical Devices Directive 93/42/EEC (as amended) All products must have their CE marking evident on the product and/or packaging.	Class I • Declaration of conformity to the Medical Devices Directive 93/42/EEC **to be provided with your Tender response.** Class I Sterile, Class I measuring, Class IIa, Class IIb and Class III • 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.** **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).