NHS Supply Chain

Appendix 3

Framework Specification for Surgical Instruments

1. Introduction

The Framework Agreement is for the supply of Surgical Instruments – Single Use Surgical Instruments, Reusable Surgical Instruments, Scalpel Blades, Scalpel Handles, and Disposable Handles, Repair and Maintenance of Surgical Instruments and Metal Instrument Recycling.

1.1 The Framework is for the following Lots:

Lot Number	Lot Title
1	Single Use Instruments & Packs
2	Reusable Surgical Instruments
3	Scalpel Blades, Scalpel Handles and Disposable Scalpels
4	Repair and maintenance of Surgical Instruments
5	Metal Instrument Recycling

1.2 Full technical specifications of the product lines awarded to the Framework Agreement must be made available to CPP LLP on request during the term of the Framework Agreement.

- CPP LLP must be notified immediately about any proposed changes to the technical specifications and/or product manufacturer of the awarded product lines throughout the term of the Framework Agreement. Any such changes must not take place without prior agreement in writing from CPP LLP.
- Product lines awarded to the Framework Agreement must be consistent with any samples supplied for testing and evaluation.
- If changes to the technical specification of any offered product line mean that the product line no longer meets the minimum requirements outlined in this Specification CPP LLP reserves the right to exclude the product line from the Framework Agreement.
- CPP LLP reserves the right to request evidence of compliance with the Specification at any time during the term of the Framework Agreement

1.3 The Specification refers to a number of standards and legislation. The list of standards/legislation/directives is not intended to be exhaustive and any relevant standard/legislation/directive (even if not stated) must be complied with.

1.4 Product lines must comply with the stated standards/legislation/directives (as amended, extended or re-enacted from time to time) and/or the relevant section within the standard/legislation/directive and/or the relevant standard within the stated suite of standards.

1.5 Evidence of compliance to the standards/legislation/directives/labour standards assurance system must be available to CPP LLP on request during the term of the Framework Agreement; in the event that sufficient evidence is not supplied CPP LLP reserve the right to suspend product lines and/or all trading activity until such evidence is made available to CPP LLP.

1.6 The Authority and/or CPP LLP (or any third party appointed at the absolute discretion of the Authority) reserves the right to test product lines throughout the term of the Framework Agreement to ensure it complies with the Specification and meets Customer requirements. If any product lines are found not to comply with these requirements, then CPP LLP reserves the right to:

- Charge for the cost of testing and any required retesting.
- Suspend the sale of the affected product line(s).
- Terminate the Framework Agreement in accordance with the provisions set out therein.

Where termination in these circumstances takes place, any stocked product lines must be collected by the Supplier or its nominated third party from the Authority's depot(s) and a full credit note must be issued to the Authority for the cost of the goods together with any other costs reasonably incurred by the Authority and/or CPP LLP as a result of such failure.

1.7 The NHS e-Procurement Strategy published by the Department of Health in April 2014 requires the NHS to adopt global standards including the implementation of GS1 product coding. Suppliers will be expected to work with the Authority, CPP LLP and Customers during the term of the Framework Agreement to meet these requirements.

2 Criteria applicable across all product lines

Standards and Legislation

STANDARD / CERTIFICATION
All products must have their CE marking clearly evident on the product and/or packaging and must conform to the relevant directive: **Medical Devices Directive 93/42/EEC (as amended) or Medical Devices Regulation MDR directive (2017/745)** During the life of this Framework all Suppliers will be required to provide evidence they are MDR compliant

2.1 Any product line that contains phthalates must be indicated on the packaging in accordance with Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC).

2.2 All product lines and packaging should be latex free where possible. Any product lines or packaging containing latex must be clearly labelled as such to inform the user.

2.3 The sterilisation process for the supply of sterile product lines must be certified by a Notified Body.

2.4 The production of stainless-steel instrumentation must be from certified steel feed stock (i.e. SAE International/AISI (American Iron and Steel) standard formulation) and a self-declaration from the Supplier stating they supply to this standard is required. CPP LLP may seek evidence if there are issues during the term of the Framework.

2.5 During the term of the Framework Agreement the substitution of stainless steel (where clinically acceptable) or polymers with an alternative material, including but not limited to polished carbon steel, low alloy carbon steel and nickel alloy for the manufacture of product lines within the Framework Agreement may be permissible provided that the Authority is made aware of the substitution, approves the change in writing and the use of an alternative material is clear to the end user Customer. Such substitutions shall be dealt with in accordance with the Additional and Associated Goods and Services provisions which are set out in Schedule 6 of Appendix 4 (Framework Agreement). For the avoidance of doubt, Applicants should not submit such alternatives for the Tender evaluation procedure for appointment to the Framework Agreement which is set out in the Invitation to Tender.

2.6 All product lines must include the following information marked on the internal instrument packaging where applicable.

- CE mark including the notified body designation number for sterile and class IIa devices.
- Single use (where appropriate).
- Description of product including size and length (where appropriate)
- Brand or trademark.
- Any products or packaging containing latex must be clearly indicated on their primary package
- Manufacturers product code printed on the individual packaging
- Manufacturer of the product stated on the packaging.
- Manufacturing date and expiry date (expiry date must be a minimum of two years hence)
- Lot/batch number
- Disposal and or recycling Instructions must be written in English or show symbols where applicable
- Storage Instructions
- Sterility label (where appropriate)

Please see supplementary information required

Suppliers must note that, where applicable, they agree to comply with and provide evidence in support of the following:

- Manufacturing and certificates of standards for quality assurance accreditation
- CE Marking; compliance with MDD/MDR
- LSAS documentation or equivalent alternative
- Classification of products (and proof of)
- All relevant academic papers and peer review journal submissions

- Case studies and papers
- Sterilisation certification

2.7 All product lines must have a shelf life of at least 2 years from date of manufacture

3 Lot 1 – Single Use Instruments and Packs

The scope of Lot 1 is for single use instruments including forceps, scissors, scalpel handles, needle holders and single use instrument packs intended for use in a wide range of medical and surgical applications that includes but shall not be limited to:

- Ear, nose and throat/Sinus/Plastic surgery.
- Cardiothoracic.
- Dermal/Podiatry.
- Obstetrics and gynaecology.
- Dental.
- Neurosurgery

3.1 All product lines in this Lot are intended to be disposed of after use and must be clearly marked as such on the product (unless limited by instrument size) and primary packaging to inform the user; they are not intended for repeat autoclaving/sterilisation.

3.2 Single use instruments must be supplied sterile and in an individual pack during the term of the Framework Agreement unless requested in a clinically clean format by the Customer (e.g. for ear, nose and throat applications where sterility may not be required) in which case it may be permissible to supply such clinically clean products under the terms of this Framework Agreement. For the avoidance of doubt, Applicants should note that they must supply sterile single use instruments in ready to use packaging for the product Tender evaluation procedure in order to be considered for appointment to the Framework Agreement, as set out in the Invitation to Tender and Appendix 9 documents.

3.3 Single use instruments should be manufactured from stainless steel or polymers as detailed in Clause 2.6: substitute materials may be considered. The only difference to this is the single use plastic forceps.

3.4 Surgical instrumentation includes but shall not be limited to:

- Scissors
- Forceps
- Plastic forceps
- Speculum
- Biopsy punch
- Nail clipper/nippers
- Retractors all types
- Needle holders
- Dissectors

- Mirror
- Probe
- Extracting forceps
- Elevator
- Burnisher
- File/foot dresser
- Burrs.
- Clip removers
- Curette
- Micro suction tubes

3.5 Scissors – A cutting instrument, consisting of two blades joined by a swivel pin that allows the cutting edges to be opened and closed manually by ring-shaped handles. The cutting action must be clean without causing tearing and the cutting blades must be correctly aligned to ensure an effective cutting action. Scissors are required in a range of sizes and designs that includes but shall not be limited to:

- Littler
- Mayo
- Plastic handled
- Strabismus.

3.6 Forceps – a form of pincer, including plastic dressing forceps, artery forceps and dissecting forceps, intended for grasping and holding applications in a wide range of medical procedures. Required in a range of sizes and designs that includes but shall not be limited to:

- Spencer Wells
- Halstead
- Hartmann
- Adson
- McIndoe

3.7 Speculum – Retracting instruments inserted into body orifices including the ear, mouth, eye, nostril, rectum and vagina during operations and examinations to both open and hold open the orifice to allow medical access. Required in a range of sizes e.g. small, medium, large and designs that includes but shall not be limited to:

- Cusco
- Graves.
- Simms

3.8 Biopsy punch – a handheld device with a plastic or steel handle and sharpened circular hollow tube tip designed to enable the removal of a tissue sample. Tips must be available in a range of diameters with a minimum size of 2mm.

3.9 Nail clipper/nipper - a handheld hinged instrument used for nail cutting consisting of a pair of handles, a joint, and a head section (with either gripping jaws or cutting edges). The

instrument can be flat or concave and is required both with and without a catch to hold them in the closed position.

3.10 Retractors – shaped instruments intended to allow body orifices and surgical incisions to be held open during an examination or medical procedure. Retractors can either be handheld with a curved/hooked end (e.g. Cheek Retractor) or pivoting with a self-retaining mechanism (eg.Weitlaner) required in a range of sizes and designs that includes but shall not be limited to:

- Kilner
- Cat's Paw
- Volkmann
- Harvey Jackson
- Norfolk and Norwich
- Elastic types

3.11 Needle Holders – a handheld instrument with ratchet closure used to hold and grip a suture during a medical procedure. The needle must not be able to turn, or twist once grasped. If soldered, tungsten carbide needle holder inserts must have no blow holes in the solder. Required in a range of sizes and designs that includes but shall not be limited to:

- Derf
- Halsey.

3.12 Towel Clips – instruments to secure towels and surgical draping during a medical procedure. Required in a range of sizes and designs that includes but shall not be limited to:

- Spring
- Backhaus.

3.13 Dissectors – a range of hand-held instruments with shaped and curved ends used in various medical procedures to separate layers of tissue within the body without cutting

3.14 Mirror – a handheld instrument with a fixed mirror at one end, used to aid visualisation of a procedure predominantly in dental work.

3.15 Probe - a range of hand-held instruments with shaped ends used in various medical procedures and for the removal of secretions e.g. ear wax

3.16 Extracting Forceps – a handheld hinged instrument with straight or angled grasping jaws, required in a range of sizes for dental extractions including roots, molars and wisdom teeth.

3.17 Elevator – dental instrumentation with a range of uses for surgical extractions including the removal of roots or parts of roots, to detach and lift tissue and to break the periodontal ligament to loosen teeth.

3.18 Burnisher – Single or double ended hand-held instruments used for dental work including contouring and sculpting, the application of amalgam and condensing composites.

3.19 File/foot dresser – abrasive bars designed for the removal of skin.

3.20 Burrs – rotary cutting tools used for a wide range of cutting, smoothing and bone harvesting applications.

3.21 Curette - a surgical instrument designed for scraping or debriding biological tissue or debris in a biopsy, excision, or cleaning procedure. The curette should have double ended blades of different sizes

3.22 Clip removers - designed to remove the clips easily following surgery. They should be robust enough to remove up to 30 clips without breaking

3.23 Surgical instrument packs must comprise of one or more of the product types listed in Clause 3.5 of this Specification supplemented by additional products and accessories (e.g. tourniquet, swabs, sample pots, gauze and gauze applicator) in order to meet the requirements of a specific medical procedure or process and will include but shall not be limited to:

- Podiatry pack
- Dental pack
- Foot dressing pack
- Single use suture instrument pack.

4 Lot 2 – Reusable Surgical Instruments

4.1 Reusable surgical instruments intended for use in a wide range of medical and surgical procedures including cutting, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after decontamination and sterilisation procedures have been carried out.

STANDARD / CERTIFICATION
All stainless-steel reusable surgical instruments must comply with the relevant elements of the following: **BS EN ISO7153-1:2001/BS5194-1:1991** (as amended) updated 2016 **BS EN ISO7153-12016** Surgical instruments. Metallic materials. Stainless steel **BS 5194-2:1989** (as amended) Surgical instruments. Specification for instruments with pivot joints (excluding cutting instruments) **BS 5194-3:1985** (as amended) Surgical instruments. Specification for dissecting forceps **BS 5194-4:1985** (as amended) Surgical instruments. Specification for scissors, shears and other jointed cutting instruments **EN ISO17664:2017** Details of the sterilisation process for reusable products

4.2 In addition to the instrument types and requirements as detailed in Section 3 of this Specification (excluding Dental product lines and Instrument Packs) reusable instruments can also include but shall not be limited to:

- Intestinal clamps
- Hard edge and ultra-cutting scissors
- Nail chisel
- Gags
- Tuning fork
- Blacks file
- Rasps and raspatories
- Chisels, gouges and osteotomes
- Maxilla instruments
- Tonsillectomy instruments
- Sterilisation/autoclave trays, baskets and containers
- Skin hooks
- Wire cutters
- Hammer
- Mallet
- Rongeurs
- Ring cutters
- Mouth props

4.3 Instructions in accordance with BS EN ISO17664:2017 (as amended) (Sterilization of medical devices or equivalent. Information to be provided by the manufacturer for the processing of sterilisable medical devices) must be provided to the Customer on request during the term of the Framework Agreement to enable reusable surgical instruments to be processed safely and continue to meet their performance specification

5 Lot 3 – Scalpel Blades, Scalpel Handles and Disposable Scalpels

5.1 Sterile and non-sterile scalpel blades. Scalpel handles to fit the blades and disposable scalpels.

5.2 Standards/Directives/Legislative requirements

STANDARD / CERTIFICATION
BS EN 27740:1992, ISO 7740:1985 Specification for dimensions of surgical scalpels with detachable blades **BS 2982:1992** Specification for materials and packaging of surgical scalpels with detachable blades **ISO 7153-1:2001** Chemical composition of grades suitable for manufacture of surgical, dental and specific instruments for orthopaedic surgery and recommendations for choice of grade for applications **EN ISO17664:2017** Details of the sterilisation process for reusable products

5.3 Scalpel blades must be supplied sterile (non-sterile if intended for post-mortem/mortuary use) designed to fit a scalpel handle and must be available in a range of shapes and lengths to enable scraping, cutting and incisions to be made in medical and surgical procedures that include but shall not be limited to:

- Podiatry
- Hernia repair
- Thoracic surgery
- Cardiac surgery.

5.4 Disposable scalpels must be supplied sterile (non-sterile if intended for post-mortem/mortuary use) and must incorporate a handle and blade and are required in both standard and safety versions.

5.5 Disposable safety scalpels must incorporate a retractable blade or sheath, safety blade or similar device in order to minimise the risk of user injury and contamination.

5.6 Reusable scalpel handles can be supplied non-sterile and must be designed to allow blades to be fitted and removed and held securely during use. Reusable scalpel handles can be manufactured from but shall not be limited to:

- Stainless steel

- Carbon steel
- Zinc plated steel
- Epoxy powder coated steel

5.7 Safety products must be designed to assist users in meeting the requirements of Council Directive 2010/32/EU and subsequent regulations intended to minimise sharps injuries in the healthcare sector.

5.8 Instructions in accordance with BS EN ISO17664:2017 (As amended) (Sterilization of medical devices. Information to be provided by the manufacturer for the processing of sterilizable medical devices) must be provided to the user on request during the term of the Framework Agreement to enable reusable scalpel handles to be processed safely and continue to meet their performance specification.

6 Lot 4 – Repair and Maintenance of Surgical Instruments

The scope for Lot 4 is for a compliant route for the repair, replacement and maintenance of surgical instruments. The scope of instruments that will require repair, replacement and maintenance is wide ranging and are instruments intended for medical and surgical procedures including cutting, scratching, scraping, clamping, retracting, clipping or similar procedures.

STANDARD / CERTIFICATION
Replacement parts must comply with BS EN ISO7153 or equivalent for the purpose of surgical instrument specifications.
Repairs must conform to BS 5194 for the chemical composition of grades suitable for manufacture, and recommendations for choice of grade for particular applications where appropriate.
Repair and/or Maintenance providers' personnel must be appropriately qualified and skilled.
Repair and/or Maintenance providers must be accredited to ISO13485 or equivalent for quality management purpose.
All repairs and maintenance must be accompanied with 6 months guarantee of the item(s) repaired or maintained

Provision of all materials, equipment, and access to approved spare parts and provision of suitably trained personnel, necessary to ensure maintenance is carried out to the manufacturer's

recommended specification, is the sole responsibility of the Supplier. All maintenance and repairs will be carried out according to the original equipment manufacturer's recommendations.

All equipment must be tested on completion of maintenance or repair to ensure compliance with required safety and electrical testing. The documentation evidencing this testing and any other relevant documentation specific to this Framework must be available upon request to CPP LLP and/or other relevant parties. Any instruments that do not meet Customer standards should be repaired or maintained again and/or replaced for no charge.

Collection and delivery service may be required for repair, maintenance and/or replacement of instruments subject to individual requests hence, the Supplier will need to collect and deliver the instruments for service/repair. The costs (if any) of the collection and delivery service shall be agreed upfront with all parties involved.

7 Lot 5 – Metal Instruments Recycling

The scope of Lot 5 is to offer a sustainable and compliant route for the recycling of metal surgical instruments encompassing the collection, transportation, segregation, treatment, disposal and trading of the resultant appropriately treated scrap metal waste. There are multiple categories/types of metal devices that are disposed of throughout a healthcare setting and these can be spread across many departments within that setting. In some situations, these devices and items are manufactured from, or contain, valuable metals that can be recovered for potential revenue generating opportunities through appropriate collaboration with specialist healthcare waste management companies.

Typical metal that will be collected from the waste stream includes single use items and any instrument made from medical grade metal or alloys that can be removed from the incineration waste streams.

These include, but are not limited to:

- Podiatry Clippers
- Curettes
- Dilators
- Forceps
- Stainless Steel Cusco Speculums
- Dissectors
- Elevators
- Dental instruments
- Scissors
- Single Use Blades

Within a typical general or university hospital single use metal items are used and disposed of by many Departments, the operating theatre will generate the vast majority (around 60-70% in weight). The amount of single use instruments and devices will vary in hospitals and other healthcare settings due to local decontamination strategies. In the event where single use devices are used in high containment areas (such as infectious disease units) these devices should not be recycled as they are intended for incineration only.

The list below is representative of typical Departments where single use metal items and devices are utilised:

- (Operational) Operating theatres
- Outpatient Departments
- Podiatry Clinics
- Maternity
- ENT
- Orthopaedics
- Obstetrics/Gynaecology
- Colposcopy
- Sexual Health Clinics
- General Surgical Laparoscopy
- General/vascular surgery
- Urological Surgery
- Surgical wards
- General wards
- Endoscopy
- Day Surgery
- Catheterisation laboratory
- A&E
- Dental/Oral Surgery/Maxillofacial Surgery

The Supplier of the specialist healthcare metal waste recycling service must ensure that all waste is collected, managed and treated by approved methods that are formally approved and licensed by the Environment Agency and/or local authority. Treatment processes operating without appropriate authorisation and licensing must not be used. The Supplier shall immediately advise all parties of any suspension, withdrawal or refusal to renew any licence, certificate or permissions applicable to carrying out the requirements of this Framework and/or any Contracts under this Framework during the term of the Framework Agreement. The Supplier will be responsible for all costs associated with finding an alternative Contractor/treatment facility if there is a failure on its part to undertake the services outlined within the specification at any time during the lifetime of the Framework Agreement. CPP LLP will require sight of the original licences and other relevant documents on a regular basis and will reserve the right to inspect any transit station and disposal facilities at any reasonable time. The Authority will not award any part of the Framework to a Supplier or sub-contractor(s) who are unable to provide formal evidence of any of the required licences necessary to operate this Framework as set out in their Tender.

Duty of Care

Suppliers must ensure that duty of care as per the code of practice published by the government is adhered to and is adequately discharged. For this, the Supplier must:

- Visit the sites, prior to offering any quotation to Customers in order to establish the suitability of their proposal for recycling of metal instruments.

- Provide a fully detailed example of an audit trail relating to the collection of all metal waste streams including appropriate method statements where significant risk is identified.

- Produce a complete procedure, which covers all the requirements of the Environmental ProtectionAct1990, as amended, the Environmental Protection (Duty of Care) Regulations 1991, as amended, including Code of Practice on Duty of Care, COSHH and the requirements of the Health and Safety at Work Act. This must include formal Risk Assessment documentation.

- The Supplier is requested to provide a 'Duty of Care' report for any organisation that they propose to use during the term of the Framework Agreement, either frequently or on a contingency basis. Reports provided must be no older than 12 months old.

Adherence to Duty of Care principles will be a continuing process throughout the duration of the Framework Agreement. The Supplier is required to amend this procedure and its reporting requirements in line with any regulatory or statutory guidance changes as applicable thorough the term of the Framework Agreement.

Healthcare Waste Categories

The Definition of Healthcare Waste is set out in the Health Technical Memorandum (HTM 07-01). Suppliers must ensure any metal instruments intended for recycling (including but not limited to collection, transportation, segregation, treatment, disposal and trading of resultant appropriately treated scrap metal waste adhere to the Health Technical Memorandum (HTM 07-01) using the classification of European Waste Catalogue (EWC).

Infectious Waste

Infectious waste is essentially a waste that poses a known or potential risk of infection, regardless of the level of infection posed but which has an additional characteristic that means it must be incinerated in a suitably licensed or permitted facility. Even minor infections are included within the definition of infections. For example; anatomical waste; chemically contaminated samples and diagnostic kits; medicinally contaminated infectious waste and; Category A pathogens.

Healthcare wastes generated from healthcare practices or produced by healthcare workers in the community are considered to be infectious waste unless assessment has taken place. This assessment is based on item and patient specific clinical assessment by a healthcare practitioner.

Municipal waste from domestic minor first-aid and self-care is of a type that does not involve recourse to a healthcare practitioner and is assumed to be non-infectious unless a healthcare practitioner indicates otherwise. Therefore, soiled waste such as nappies, sanitary products and plasters are not considered to be infectious unless a healthcare practitioner gives the producer advice to the contrary.

Similarly, municipal type waste from industrial and commercial premises is assumed to be non-infectious providing that a risk assessment has been conducted. Therefore, soiled waste such as sanitary products and plasters are not considered to be infectious unless a healthcare practitioner gives specific advice to the contrary.

Waste contaminated with non-infectious bodily fluids is capable of causing offence and therefore requires appropriate packaging to alert those in the waste management chain of the contents. The HTM 07-01 V2 document identifies such waste as offensive/hygiene waste.

Anatomical Waste

Anatomical Waste includes recognisable body parts and placenta, requires disposal by incineration in a suitably licenced or permitted facility. Anatomical Waste includes:

- all human and animal tissue, as this is considered anatomical waste (being part of a body or organ), with the exception of very small unidentifiable pieces of skin or flesh incidentally removed from treatment of wounds or during very minor surgery (for example mole removal, nail clippings etc);
- pieces of waste bone/tissue from procedures perfumed during, but not limited to, orthopaedic, spinal, neurosurgical, maxillofacial, dental, oral, podiatric surgery.

Hazardous Healthcare Waste

Hazardous Health Care waste included within this Framework is that defined by current and any future legislation. Specific categories of Hazardous Health Care Waste included within this Framework include but are not limited to:

- Healthcare waste contaminated with radioactive material
- Infectious waste contaminated with cytotoxic and/or cytostatic medicinal products
- Sharps contaminated with cytotoxic and cytostatic medicinal products
- Infectious and other waste requiring incineration including anatomical waste, diagnostic specimens, reagent of test vials and kits containing chemicals
- Amalgam waste from dental care.
- Subject to revised legislation and regulations, these categories are subject to alteration during the term of the Framework Agreement.

Container Policy

Suppliers must ensure the containers are compliant to ISO 23907-2 standard. Containers must be clearly labelled and easily identifiable in line with Health Technical Memorandum 07-01 V2: Safe Management of Healthcare Waste. Any labels supplied are to be within the cost of the service.

The Supplier of this Lot 5 service will supply an agreed number of containers at the commencement of an agreement with Customer(s) and these will fully conform to the Health Technical Memorandum 07-01 V2 and meet all requirements of current legislation (i.e. UN Guidance and Markings) such as Health and Safety Executive (HSE)'s UN3291 for infectious substances, clinical waste and diagnostic specimens to classify goods that contain infectious substances. Containers must be fit for the purpose of use with locking lids, keys, towing bars etc. as required by the Customers. Containers must be fully maintained and serviced by the Supplier at all times and must be replaced without additional costs to Customers or the Authority. The Supplier shall immediately (within one working day) replace damaged containers on a one for one basis and the damaged containers must be removed from the relevant site without delay.

All Containers must be cleaned and disinfected by the Supplier after each service exchange as a guide and without limitation this requires the bins to be free of visible soiling inside and out and odour free. The containers will remain the property of and be maintained by the Supplier throughout the term of the Framework Agreement. The Supplier will be required to provide containers in excess of normal requirements to accommodate emergency overflow of Healthcare waste.

Transport of Waste

Suppliers shall at all times maintain a comprehensive transportation plan giving details of routes, collection points, timetables, vehicles and driver details. The transportation plan should allow sufficient flexibility to accommodate any reasonable special needs that Customers may have. The Supplier shall consult the Customer regarding any alterations and agreement should be provided in writing by the Customer before any changes are made.

All vehicles used for providing the services are to be roadworthy in accordance with the Road Traffic Acts and as appropriate be properly licensed by the Local Authority and where appropriate be of a type that conforms to current Motor Vehicle Regulations (i.e. Motor Vehicles (Construction and Use) Regulations, the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004 etc) and any relevant future regulations during the term of the Framework Agreement.

Vehicles must be maintained to a high standard of reliability and roadworthiness and will be subject to inspection at any reasonable time and may (but not unreasonably or vexatiously) instruct the Supplier not to use the said vehicles in the provision of the services. All vehicles used must conform to the Motor Vehicles (Construction and Use) Regulations.

The interior and exterior of all vehicles must be kept clean and tidy. The Supplier will be required to demonstrate that it can provide adequate cover for the non-availability of vehicles for any reason. The condition of the vehicles shall at all times, be at the expense of the Supplier and be appropriately licensed and insured.

The Supplier shall ensure that the necessary Transport Documentation required to support the carriage of UN3291, Clinical Waste, Unspecified and N.O.S. (as required under the CDG Road Regulations 13(2) is completed in order to ensure that no parties are in breach of their Duty of Care.

The Supplier is to comply with the current relevant legislation (and any relevant future legislation) relating to the disposal of Healthcare waste, in accordance with Department of Health guidelines including Health Technical Memorandum HTM 07-01 V2: Safe Management of Healthcare Waste.

In the event that the Supplier wishes to utilise alternative site(s)/facilities all parties to the Contract and CPP LLP must be notified in writing.

All waste management operations must be carried out in accordance with all current relevant legislation. Evidence of this must be auditable and available on demand by CPP LLP.

Sub-Contracting

Suppliers shall indicate within their tender return (as part of the supplementary information required response) any aspects of the Framework they would intend to sub-Contract and/or employ a third party to fulfil the service(s).

The Supplier shall not sub-contract any aspect of Lot 5 – metal instruments recycling during the term of the Framework Agreement without the prior consent in writing from the Authority.

Supplier's Staff

Suppliers shall ensure that every person employed by it and / or sub-contractor(s) employed for the provision of metal instrument recycling, are at all times properly and sufficiently trained by having participated in a formal training programme prior to commencing work. Details of training records should be available as requested by CPP LLP.

Staff appointed by the Supplier and / or sub-contractor(s) and / or temporary staff must be aware of all relevant rules and procedures concerning Health and Safety at Work and the recording of all accidents and untoward occurrences involving metal instruments recycling.

Customer(s) reserve the right to request the removal of staff who fail to carry out the service to the standards required by the Customer and/or the Authority.

The Supplier shall fulfil the requirements of the Customer(s) with a minimum of disruption. Specific attention should be drawn to the following:

- Not to convey any articles to or from a patient or have any dealing with any patient unless requested by the authorised Officer;
- Not to trespass on Customer's property but confine itself strictly to the locality of its work;
- The Supplier's attention is drawn to the provisions of the Mental Health Act 1983 which, lays down penalties to which persons employed in Mental Health Hospitals are liable upon conviction for misconduct with patients. A copy of the Act may be seen in the office of the Unit Manager and Suppliers are reminded that ignorance of the law is not regarded as a defence in the Courts;
- The Supplier and its relevant staff employed on this Framework must at all times be mindful of the need to respect patient confidentiality and should not interact verbally or physically with patients.

The Supplier shall be liable for both authorised and unauthorised acts of its employees whilst carrying out their duties in line with the Framework Agreement and Contract.

The Supplier shall ensure that:

- Every person newly recruited to be employed by the Supplier and / or sub-contractor(s) in and about the provision of the services shall, at the Supplier's expense, at the commencement of a new Contract or that person's employment (whichever shall be the latter) be medically screened.
- Any employee shall be excluded from the relevant site when suffering from any infectious or communicable disease.

Spillage/Accidents

Spillages and/or accidents must be immediately reported to all parties under the Contract (to be provided during implementation) and confirmed in writing within 48 hours.

Costs arising to clear spillages, bursts or accidents that occur at fault of the Supplier shall be not be charged to Customer and/or the Authority. Costs arising to clear spillages, bursts or accidents that occur at fault by Customers **must** be provided and accounted for within the commercial offer (pricing schedule) of this Framework. Suppliers are deemed to have included these costs within the commercial offer.

Tracking and Audit Requirements

The Supplier will put in place a system of tracking and auditing container movements which is acceptable to and easily monitored. This system which may be by bar coding or a numbered container system must be maintained by the Supplier. It should permit the identification and monitoring of all containers, from the yard, to the wards/departments, the return to waste yard, to the carrier's vehicle and through to the treatment site.

CPP LLP and relevant parties will require sight of the original licences and other relevant documents on a regular basis and will reserve the right to inspect licences, permits and/or any transit station and disposal facilities at any reasonable time

The Supplier should ensure that the containers are clearly labelled, and they are easily identifiable as metal instrument recycling containers. Any labels supplied are to be within the cost of the service. The Supplier will supply an agreed number of containers which are clean and lockable at the commencement of the Contract. Containers must be fully maintained and serviced by the Supplier at all times and must be replaced without additional costs to Customers or the Authority when required. The Supplier shall immediately (within one working day) replace damaged containers with undamaged one and the damaged bins must be removed from the relevant site without delay. All containers must be cleaned after each use to ensure full decontamination by the Supplier. The Supplier must have in place a fully auditable identification and tracking system from point of collection to disposal.

8 Packaging

All packaging must comply with the relevant UK Medical Device Directive at all times. It is the responsibility of the Supplier to ensure that packaging is appropriate for the product being transported in terms of handling, storage and ease of use by the Participating Authority.

Product packaging for products should state the following:

- Product name
- Product code
- Pack Quantity (where applicable)
- Expiry or use by data
- Barcode / GS1 code
- CE Mark
- Recyclable instructions for packaging
- Sterile indicators

- Single Use/Reusable
- labelled latex free

All sterile packed products must be handled and sealed in compliance with ISO 11607-1 as a standard. It is the responsibility of the Supplier to ensure that products are packaged to ensure preservation of a sterile field as appropriate for the handling and use of the product. It is required that all sterile products are clearly labelled as sterilised.

In any event that the Participating Authority has cause to consider packaging, labelling or sterile containment to be damaged or indicative of inference it reserves the right to reject and return any product; including those associated with the same or similar batches and will be reimbursed in full for the costs of the Goods and associated charges.

9 Product Trials/Evaluations

Participating Authorities reserve the right to undertake trials and evaluations of alternative Suppliers' products. Any trials and evaluations conducted will follow the individual Participating Authority's policies and protocols.

Suppliers may provide the Participating Authorities with the option to participate in a trial. Written authorisation must be obtained from the Participating Authority prior to the commencement date of any trial. The Participating Authority shall not be liable for any costs incurred by the Supplier in relation to the trial.

The Supplier is expected to support any required product trials or clinical evaluations as requested by the Participating Authority and must provide samples to enable the Participating Authority to carry out required evaluations. To enable the Participating Authority to manage and complete a meaningful evaluation, product training and clinical guidance must also be provided.

In exceptional cases where there is a significant cost associated with undertaking any trial a Supplier will be within their right to negotiate a reasonable charge in advance of the trial commencing. For the avoidance of doubt this is only in exceptional circumstances and once agreed the charge will not increase regardless of the trial length.

Full and effective training must be given to each member of staff associated with the trial and at respective levels / requirements prior to any clinical trial being conducted.

Trials will be time-bound, and this will be clearly agreed between the Supplier and affected parties within the Participating Authority(s). The Supplier must inform CPP LLP of the trial start date and duration.

The Supplier is required to supply appropriate supporting documentation, including evaluation forms if requested to do so. As a minimum, it is expected that supporting documents establish the duration, content, cost, desired outcome and method for managing the trial to the Participating Authority.

The Participating Authority will provide feedback to Suppliers on clinical trials of any samples evaluated.

10 Changes Throughout the Framework

i. New Products / Range Extensions

Suppliers must inform Participating Authorities(s) and CPP LLP in writing of any new products which they wish to include on the Framework for consideration/evaluation and subsequent agreement by the Authority.

The Supplier shall request additional products to be added to their commercial offer only for Framework Lots for which they were awarded.

The Supplier must inform CPP LLP and individual Participating Authorities concerned in writing of any proposed changes to the specification of the goods being supplied under the Framework, including proposed changes to packaging quantity or format, for consideration by the Participating Authority. Notification of any such proposals shall be made at least three months prior to the proposed implementation date of any changes.

The price of additional products shall be in line with the discount structure contained within the price agreement and will be reviewed and accepted by the CPP LLP Category Management Team.

The Supplier shall inform CPP LLP in writing of any additional products which it wishes to include on the Framework.

Notification of the request to add products shall be by e-mail to CPPSupport@supplychain.nhs.uk in the format determined by CPP LLP.

Where relevant, Suppliers must adhere to the protocol set out in Beyond Compliance.
http://www.beyondcompliance.org.uk/

CPP LLP shall notify the Supplier that products have been added to the Framework. Any products added are at the discretion of CPP/the Authority.

ii. Product changes

The Supplier should have and maintain a policy that governs the managed specification changes of products within its portfolio. The Supplier is required to inform CPP LLP in writing of any proposed specification changes to products being supplied under the Framework, including proposed changes to packaging quantity or format, for consideration by CPP LLP. Notification of any such proposals shall be made at least three (3) months prior to the proposed implementation date of any changes.

The Supplier shall confirm provision for future technological advances such as advances or alterations in materials of construct, sizing, anatomical improvements, imaging compatible products, etc. and associated disposable / non-disposable instrumentation that may be used for various procedures within elective and emergency surgery which relate to the product areas described in this Specification.

All information regarding the changes including, but not limited to sizing, packaging, unit of measure etc. shall be notified via e-mail to CPPSupport@supplychain.nhs.uk

CPP LLP shall notify the Supplier that product changes have been applied to the Framework.

iii. Product obsolescence – Delisting

The Supplier shall notify CPP LLP in writing of any proposed product deletions at least three months prior to the proposed implementation date to CPPSupport@supplychain.nhs.uk

The Supplier shall notify CPP LLP in writing if the product deletions will affect the purchase of associated products and provide a report of Participating Authority usage associated with those products in the rolling 12 months to the date of the notification.

The Supplier must confirm that any affected customers have been notified of the intention to delist and advised of any required action that needs to be taken.

The Supplier shall advise of the "reasons" for the request to delete/delist the products.

The Supplier shall notify CPP LLP in writing of any alternative product to those being delisted. Alternative products may not be "like for like" but may facilitate the same clinical outcome.

Once approved, the affected pricing schedule must be resubmitted to CPP LLP with all delisted product NPC highlighted in red and with all pricing in each cell replaced by the word "obsolete".

Once delisted, products may only be re-enlisted at the equivalent or reduced price, prior to delisting.

CPP LLP shall notify the Supplier that products have been removed from the Framework.

11 Business Continuity

The Supplier must have in place a suitable Business Continuity plan to ensure continuity of supply in the event of a disruption to the Supplier's manufacturing or distribution process:

- of supply in event of a disruption to Supplier's manufacturing or distribution channels
- of service in the event of a disruption to Supplier's resource
- of supply & services from 3rd parties
- of supply & service in the event of adverse weather conditions
- of supply in the event of a pandemic

Contingency planning shall include, but not be limited to: -

- Evacuation of Supplier premises
- IT and / or telecoms failure
- Industrial Action (internal or external influences)
- Device / product recall
- Production failure
- Working from home

In the event of a Major Incident or local emergency involving an NHS body, the Supplier shall facilitate supply requests by telephone from the Authorised Person(s).

The Supplier must provide copies of its Business Continuity Plans and/or Risk management Policy towards supply chain continuity as part of its Tender submission.

12 Brexit

Suppliers must have in place Business Brexit Plans and Supply Chain maps as part of their policies.

Suppliers are required to include a copy of their Brexit plans as part of their Tender submission covering, but not limited to:

- Location of manufacturing sites and availability after Brexit
- Warehousing and distribution plans
- Stock planning
- Cross boarder logistic planning
- Impact of restrictive immigration regimes on workforce

If a Supplier requests a price change resulting from changes in Government legislation or regulatory requirements that were unforeseen or unquantifiable at the time of the Framework Agreement award, the Supplier must produce financial records, sufficiently detailed, to prove the level of impact upon it and submit to CPP LLP for consideration.

13 Stock Route

If a supplier's product is awarded onto the stock route, the Supplier must hold as a minimum 4 weeks' worth of stock of the same product in a U.K. warehouse. The minimum 4 weeks' worth of stock will be based on the demand of the first 3 months from a prior rolling 6 months period. This stock must not be with the Supplier's distributor and/or a third party but must be in legal ownership of the Supplier and solely for the benefit (i.e. supply) of NHS Supply Chain. NHS Supply Chain reserve the right to audit a supplier against this requirement if they are awarded or before awarding them to Stock route.

14 Modern Slavery Assessment Tool (MSAT)

MSAT is a Government tool which assess the capacity of an organisation to manage and prevent the risks of modern slavery and provides clear recommendations with guidance. This assessment tool is being adopted throughout the public sector of which the NHS is a part.

There is an acknowledgement that relevant commercial organisations as defined by section 54 ("Transparency in supply chains etc.) of the Modern Slavery Act 2015 have annual reporting requirements and those commercial organisations with a turnover of less than £36m are not legally obliged to report.

The purpose of Modern Slavery Assessment is to identify and manage modern slavery risks and therefore a tool to assist with continual improvement over the term of the Framework Agreement and beyond.

The MSAT report scoring mechanism is:

Red	0 – 19 %
Orange	20 – 39%
Yellow	40 – 69%
Green	70 - 100%

Requirement 1 by 4th October 2021
All Suppliers are required to undertake an initial MSAT assessment

Once the initial assessment is complete, a bespoke report containing useful guidance, recommendations and practical tools to help make improvements will be provided.

Requirement 2 by 7th February 2022
SME Suppliers are required to be at Yellow

Suppliers falling under the definition in Section 54 of the Modern Slavery Act 2015 are required to be at Green.

Requirement 3 by 2nd May 2022
SME Suppliers are required to be at Green by 2nd May 2022 and annually thereafter demonstrate an incremental improvement.

Removal from Framework
Suppliers which have not reached a "Green" rating by 2nd May 2022 shall be deemed non-compliant and be removed from the Framework Agreement.

Appendix 3b

3B FRAMEWORK AGREEMENT SPECIFICATION – TENDER REQUIREMENTS

1. Introduction

1.1. Evidence of compliance to the standards/legislation/directives listed in the tables below must be provided as part of the Tender submission (unless otherwise specified), where they apply to the products tendered.

1.2. Files uploaded as part of the Tender submission must be clearly named with the directive / standard to which they relate as well as clearly identifying which product / products they cover.

1.3. Where standards are not applicable to specific products then signed declarations stating this is the case must be provided with the Tender submission.

2. Criteria applicable across <u>all Lots</u>

2.1. Standards/Directives/Legislative requirements

STANDARD / DIRECTIVE / LEGISLATION	TENDER REQUIREMENTS
Medical Devices Directive 93/42/EEC (as amended) or Medical Devices Regulation MDR directive (2017/745) **During the life of this Framework all Suppliers will be required to provide evidence they are MDR compliant** All products must have their CE marking clearly evident on the product and/or packaging.	Class I Sterile, Class I measuring, Class IIa, Class IIb and Class III CE certificate from a notified body to be provided with the Tender submission.

2.2. Identifies the presence of natural rubber latex where applicable.

3. Stainless Steel Product Lines

3.1. Standards / Directives / Legislative requirements

STANDARD / CERTIFICATION	TENDER REQUIREMENTS
The production of stainless-steel instrumentation must be from certified steel feed stock (i.e. SAE International/AISI (American Iron and Steel) standard formulation) a self-declaration from the Supplier stating they supply to this standard is required. CPP LLP may seek evidence if there are issues during the term of the Framework Agreement	A Certificate of Analysis for a feedstock purchase within the 6 months prior to the Tender publication date **to be provided with the Tender submission.**

4. Lot 2 – Reusable Instruments

4.1. Standards / Directives / Legislative requirements

STANDARD / CERTIFICATION	TENDER REQUIREMENTS

BS EN ISO7153-1:2001 / BS51941:1991 (as amended) Surgical instruments. Metallic materials. Stainless steel (or equivalent)	An Independent Laboratory Report confirming compliance for a product type as listed in Clause 3.10 or Clause 4.3 of the Framework Agreement Specification **to be provided with the Tender return. (Must be less than 12 months old).** **Where not applicable** Provide a statement to confirm that this standard is not applicable to the Applicant's products. The Applicant will need to declare for each Product Line submitted.
BS 5194-2:1989 Surgical instruments. Specification for instruments with pivot joints (excluding cutting instruments) (or equivalent)	Self-declaration of Conformity **to be provided with the Tender return (if applicable).** **Evidence will be requested as part of the tender award process.** **Where not applicable** Provide a statement to confirm that this standard is not applicable to the Applicant's products. The Applicant will need to declare for each product line submitted.
BS 5194-3:1985 Surgical instruments. Specification for dissecting forceps (or equivalent)	Self-declaration of Conformity **to be provided with the Tender return (if applicable).** Evidence **will** be requested as part of the tender award process. **Where not applicable** Provide a statement to confirm that this standard is not applicable to the Applicant's products. The Applicant will need to declare for each product line submitted.
BS 5194-4:1985 Surgical instruments. Specification for scissors, shears and other jointed cutting instruments (or equivalent)	Self-declaration of Conformity **to be provided with the Tender return (if applicable).** Evidence **will** be requested as part of the tender award process. **Where not applicable** Provide a statement to confirm that this standard is not applicable to the Applicant's products. The Applicant will need to declare for each product line submitted.

BS 11607 -1 **Goods in sterile state all labelling clearly identify its conformance & be packaged to an appropriate standard. Thus, ensuring the preservation of a sterile field as appropriate for the handling & use of the product.**	Self-declaration of Conformity **to be provided with the Tender return (if applicable).** **Evidence will be requested as part of the tender award process.** **Where not applicable** Provide a statement to confirm that this standard is not applicable to the Applicant's products. The Applicant will need to declare for each product line submitted.
BS EN ISO 9001:2012 & ISO 13485:2016 **Quality Assurance Systems in place**	Self-declaration of Conformity **to be provided with the Tender return (if applicable).** **Evidence will be requested as part of the tender award process.** **Where not applicable** Provide a statement to confirm that this standard is not applicable to the Applicant's products. The Applicant will need to declare for each product line submitted.
BS EN ISO 7151:1988 **Surgical Instruments – non cutting, articulated instruments – general requirements & test methods**	Self-declaration of Conformity **to be provided with the Tender return (if applicable).** **Evidence will be requested as part of the tender award process.** **Where not applicable** Provide a statement to confirm that this standard is not applicable to the Applicant's products. The Applicant will need to declare for each product line submitted.
ISO 14971:2019 Medical devices — Application of risk management to medical devices	Self-declaration of Conformity **to be provided with the Tender return (if applicable).** **Evidence will be requested as part of the tender award process.** **Where not applicable** Provide a statement to confirm that this standard is not applicable to the Applicant's products. The Applicant will need to declare for each product line submitted.

5. Lot 3 – Scalpel Blades, Scalpel Handles and Disposable Safety Scalpels

5.1. Standards / Directives / Legislative requirements

STANDARD / CERTIFICATION	TENDER REQUIREMENTS
BS EN 27740:1992, ISO 7740:1985 Specification for dimensions of surgical scalpels with detachable blades (or equivalent)	Self-declaration of Conformity **to be provided with the Tender return** (if applicable and not already provided). **Evidence will be requested as part of the tender award process**. **Where not applicable** Provide a statement to confirm that this standard is not applicable to the Applicant's products. The Applicant will need to declare for each product line submitted.
BS 2982:1992 Specification for materials and packaging of surgical scalpels with detachable blades (or equivalent)	Self-declaration of Conformity **to be provided with the Tender return** (if applicable and not already provided). **Evidence will be requested as part of the tender award process**. **Where not applicable** Provide a statement to confirm that this standard is not applicable to the Applicant's products. The Applicant will need to declare for each product line submitted.

6. Lot 5 – Metal Instruments Recycling

SUPPLEMENTARY INFORMATION REQUIRED

• Please submit copies of all certificates and licences, as relevant to this Lot 5 for metal instruments recycling, in particular:
  • Waste Carrier Registration Certificate(s)
  • Exemption(s) from waste management licensing
  • Transfer Station Licence(s)
  • Waste Management Licence(s) Healthcare Waste and Hazardous Healthcare Waste Streams
  • Integrated Pollution Prevention and Control (IPPC) Permits & Pollution
  • Prevention and Control (PPC) Permit(s)
 	
• Please provide details/copies of any other licences you believe are relevant to this Framework.
 	
• Please provide details of the quality assurance system and/or accreditations (including copies of certificated evidence) for the purpose of recycling metal instruments.