Appendix 3

TECHNICAL/QUALITY SPECIFICATION
MINIMALLY INVASIVE SURGERY

CPP LLP on behalf of the Authority is seeking to establish a **multi-source** framework agreement for **Minimally Invasive Surgery,** which will provide a comprehensive range of products suitable for use across the NHS in England.

The scope of this Framework will include:

- **Clips and Clip Appliers**
- **Energy Based Devices**
- **Surgical Stapling Devices**
- **Laparoscopic Instrumentation**
- **Trocars**
- **Abnormal Uterine Bleeding Systems**

This Specification will be inserted into Schedule 5 of the Framework Agreement Appendix 4

(Specification and Tender Response Document).

This Framework Agreement will replace the two current Framework Agreements below ("Existing Frameworks"):

- Minimally Invasive Surgery provided by NHS SC February 2017 - FAG 16308
- Theatre Surgery Consumables provided by NOE CPC February 2017 - CPC 01302

INTRODUCTION TO THE PROCUREMENT

This procurement supports the aims of the Department of Health and Social Care's - The Operating Model (OM) for NHS Procurement developed to transform the landscape of NHS Procurement.

The OM is a strategic response to enhancing procurement efficiency and effectiveness across the NHS, as laid out in the Carter Report, to:

- benefit the NHS as a whole;
- benefit all Participating Authorities/NHS Participating Authorities regardless of size;
- benefit the procurement profession; and
- benefit Patients.

Whilst we recognise that the introduction of the OM represents a significant change in the way in which the NHS purchases goods, and this will have potential impacts on Suppliers' ways of working, we believe that the OM creates opportunities for Suppliers, for example:

- a reduced burden of participating in procurement exercises, as the number of competing frameworks is reduced;
- the inclusion of clinical expertise embedded into the towers means that we will be buying those products that the NHS wants rather than simply the cheapest;
- commitment deals will make it easier for Suppliers to plan their business and outputs, and to reduce internal costs and this also means more certainty and predictable cash flow; and
- there is a much clearer route for innovation.

On 1 April 2018 the new operating model went live. The new supply chain service is designed to help the NHS deliver clinically assured, quality products at the best value through a range of specialist buying functions. The NHS has the potential, through greater collaboration, to improve the NHS's purchasing power on a national scale and deliver better value for money for NHS Participating Authorities and the tax payer.
Oversight and operational management of the new model is delivered by a new management function, Supply Chain Coordination Limited (SCCL), a Limited company wholly owned by the Secretary of State for Health and Social Care and forms part of the NHS family.

The OM is organised into eleven Category Towers covering medical, capital and non-medical areas of procurement spend. This procurement relates to Tower 2 – Sterile Intervention Equipment and Associated Consumables.

CPP LLP acting on behalf the Authority are managing the re-tender and delivery of **Minimally Invasive Surgery Framework** Agreement for the English NHS and acting as their agent in all matters.
Suppliers accepted on to the Framework Agreement shall provide goods and services to the NHS and:

I. any NHS Trust (Participating Authority) shared service, purchasing or Contracting Authority;
II. any other NHS entity or Local Authority;
III. any government department agency or other statutory body;
IV. any private sector entity in the UK healthcare sector providing outsourced services to NHS patients under NHS Terms; and/or
V. any third party / managed service acting on behalf of the NHS.

and any statutory successor to any of the above as a result of statutory re-organisation or otherwise.

The purpose of the **Minimally Invasive Surgery** Framework is:

to assure the NHS that Framework Suppliers are compliant to clinical and industry standards and are therefore safe to contract with:

- build sustainable partnerships between the NHS and Suppliers which ensures the NHS benefit from ongoing cost effective, value added products and services whilst enabling Suppliers' continued profitable growth within this market area;
- to provide the NHS with the best market price available - to set the commercial parameters in how pricing can be applied for the NHS which is consistent across Industry, in a fair and transparent way;
- transformation of the NHS landscape - championing rationalisation, standardisation, co-operation and collaboration to affect patient pathways and clinical outcomes;
- lay the foundations for efficiency savings and process improvements beyond the price of products;
- to support facilitation of changes in clinical practice, new technologies and new treatment;
- to provide a sustainable and robust supply of products to the NHS;
- to enable the use of data to improve health outcomes; and
- ensure effective characterisation of Products and cataloguing for the NHS.

Working with Participating Organisations and Industry under the Framework Agreement

On behalf of the Authority, CPP LLP aims to work collaboratively and transparently with the NHS and Industry to enable an effective and compliant route to market for the NHS. CPP LLP has established a team which will focus on driving value across the NHS through effective category management and clinical engagement. This team includes the following functions which will engage at varying levels across the NHS and Industry:

- Data analysts – responsible for reviewing spend data and running any required analysis.
- Contracting – responsible for procurement processes, catalogue management and supporting the category management team.
- Category Managers – responsible for contributing to the ongoing development of the category strategy and working with Participating Authorities to establish their baseline, develop work plans and manage projects at individual Participating Authorities and across any collaborative working organisations.
- Clinical Engagement and Implementation Managers (CEIM) – responsible for contributing to the ongoing development of the category strategy and engaging with NHS clinicians regarding clinical procedures, informing them of products from the market and supporting the surgical teams to find an optimum solution for their patient care.
- CPP LLP also works with SCCL customer engagement team whose local account managers support Participating Authorities at local level to assist with transition to the CTSP/NHS Supply Chain transacted model.

CPP LLP's process of engaging with Participating Authorities is designed to ensure the timely delivery of projects across the NHS in collaboration with Industry. This involves, but is not limited to the following:

1. Identify and Profile the Participating Organisation(s).
2. Meet clinical, procurement & business leads to discuss and scope the project.
3. Obtain usage, analysis of 12 months activity data with all Suppliers.
4. Commercial analysis of the opportunities available for individual or groups of Trusts to show the potential benefits on different scenarios.
5. Participating Authorities may request to access all or part of the Framework Agreement subject to outcomes, as described above in point 2. If further analysis is required and the Participating Authority wishes to further consolidate their expenditure:
    a) CEIMs work closely with the clinical team to identify the correct choice of product for the specific requirement/procedure.
    b) Industry are engaged to align and support the clinical department

c) Supplier events may be facilitated
d) Expenditure reviewed and forecasted usage (and commitment if relevant) translates into subsequent and appropriate commercial offering.

1. Framework Structure

The Framework Agreement will be for a term of **4** years **(2-year** fixed period with the option to extend for a further **24** months).
The Framework will comprise the following lots:

Lot Number	Lot Title
Lot One	Clips and Clip Appliers
Lot Two	Energy Based Devices
Lot Three	Surgical Stapling Device
Lot Four	Laparoscopic Instruments
Lot Five	Trocars
Lot Six	Abnormal uterine bleeding products

Bidders may bid for one or more lots.

Tender Response Questions within Appendix 11 sets out with several generic questions applicable to all 6 Lots and Lot specific questions.
Note, Appendix 11 is **NOT** to be completed by Bidders, this just provides visibility of all Technical Questions and the scoring methodology used to form part of the evaluation.

The Supplier **MUST** respond to all generic questions and the questions specific to each of the Lots it is bidding for on the e-Tendering Portal.

The Supplier **MUST** complete each tab within the Price Schedule (**Appendix 6**) in relation to the Lots it is bidding for.

Current Spend

The below shows the historical annual sales through the Existing Frameworks - Minimally Invasive Surgery and Theatre Surgery Consumables £79.4 million

Lot Number	Lot Title	Annual Sales
Lot One	Clips and Clip Appliers	£6.7m
Lot Two	Energy Based Devices	£23.8m

Lot Three	Surgical Stapling Devices	£26.6m
Lot Four	Laparoscopic Instruments	£6.6m
Lot Five	Trocars	£10.8m
Lot Six	Abnormal uterine bleeding products	£4.9m

2 NHS

2.1 NHS Mergers and Acquisitions

NHS transformation has resulted in NHS organisations merging and, in some instances, one organisation has acquired all or part of another NHS entity.

Where a merger or acquisition affects the contracting position of an organisation using the Framework, the Supplier shall be advised that a re-calculation of the activity profile shall be undertaken.

2.2 Collaborative Procurement

Partnerships and collaboration are at the heart of NHS reforms in England.

Collaborative working within the NHS has been promoted to help meet a 'triple challenge' set out in the NHS Five Year Forward View – better health, transformed quality of care delivery, and sustainable finances.

The Supplier shall be required to provide data in relation to these groups and future groups formed to support NHS collaborative working.

2.3 Collaborative Working by Participating Authorities

The Commercial Schedule indicated in Appendix 6 'Pricing Schedule' identifies banded pricing for individual Participating Authorities and those working collaboratively who are prepared to commit a minimum of 12 months usage. Tabs Lot 1 through to Lot 6 allows Suppliers to submit additional discounts for an individual Participating Authority and/or Collaborative reaching their required threshold bands

The eligibility for multiple legal entities acting collaboratively shall be based on the following:

- Participating Authorities regarded as a single legal entity, prior to final merger. (e.g. NHS Trusts which have merged or have formally satisfied the Supplier, through written commitment, of their intention to merge at a given date).
- Participating Authorities regarded as a single contracting authority.
- Participating Authorities operating under a shared service. (e.g. Trusts with one central purchasing department but not necessarily one delivery point)
- Participating Authorities who are part of a Sustainability and Transformation Partnership (STP)

- Any two or more Participating Authorities who wish to commit as a group and satisfy certain requirements as outlined below:

Two or more NHS Trusts qualify:

- Participating Authorities will look to access such commercial offerings as part of any product rationalisation processes across single / multiple Lots (unless already in a common rationalised supply relationship);
- Rationalisation may not result in outright majority supply, but a solution for a common product range across the Trusts in scope;
- Participating Authorities wishing to access the Framework as a group, must be geographically close to one another to allow the Supplier to optimally service those Participating Authorities;
- Participating Authorities may wish to contract together linked by speciality whereby niche or more specialist care is taken into consideration and requires joint activity;
- Commitment to volume / spend and to term must be offered, consistently across the group subject to Supplier offers;
- Commitment must be approved by the relevant Participating Authority boards, and each Participating Authority should sign the commitment access form at finance, procurement and clinical lead level;
- In offering commitment, each Participating Authority agrees to share full liability for the duration of the commitment.

Sustainability and Transformation Partnerships (STPs) are designed around the needs of whole areas, not just individual organisations.

There are currently 44 STP areas covering all of England, where local NHS organisations and councils have drawn up proposals to improve health and care in the areas, they serve by working together. An STP is not a legal entity – organisations within the STP "(The Authority)" will determine their own Memorandum of Understanding prior to entering into a contract with a Supplier.

3. General Requirements – Applicable to all 6 Lots

The following details the specification of requirements that are generic to all 6 Lots.

The Supplier must respond to the corresponding questions in **Appendix 11 'Non-Financial Questions'** confirming compliance with the generic specification requirements, where applicable. **All questions must be answered on the e-Tendering Portal**.

If, during Award, or subsequent to Award a Supplier is found to have misrepresented their compliance with the Specification, the Supplier will be suspended from the Framework Agreement pending investigation, which may result in permanent removal from the Framework Agreement. Any Participating Authorities engaged with that Supplier will be notified accordingly as soon as issues concerning misrepresentation of compliance is identified.

Suppliers are subject to an on-going obligation to notify CPP LLP of any material changes in their identity, financial or other circumstances. This includes, but is not limited to, changes in the identity of partner organisations or sub-contractors or the ownership or financial or other circumstances thereof and solvency of the Supplier or their agents.

CPP LLP shall be notified of any material change as soon as it becomes apparent.

Failure to notify CPP LLP or to comply with these provisions may lead to a Supplier being liable for disqualification from the Framework Agreement.

3.1 Compliance – Medical Devices

Medical Devices Directive 93/42/EEC and the Medical Devices Regulation 2017/745.
It is a mandatory requirement that all Suppliers comply with and supply products in line with the Medical Devices Directive 93/42/EEC (and any other European Directives applicable to the products supplied under this Framework) as implemented in UK law by the Medicines and Healthcare products Regulatory Agency, except when supplied under a clinical trial.

For reference, guidance can be found here:
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Regulations relating to the safety and performance of medical devices in the EU were harmonised in the 1990's following the New Approach on legislative principles. The regulation aims to ensure a high level of protection for human health and safety and good functioning of the Single Market.

During the transition period: -

- Conformance to Directive 2007/47/EC shall be deemed a minimum requirement.
- Suppliers shall advise CPP LLP on attainment of full compliance.

All equipment and products complying with the Medical Devices Directive 2007/47/EC shall bare valid CE markings or UK equivalent CE marking and compliant to MHRA and EUCOMED.

Suppliers shall; where applicable; comply with and provide evidence in support of the following Industry requirements

- Manufacturing and certificates of standards for quality assurance accreditation
- CE Marking; compliance with MDR
- Certification / MSAT
- Compliance with MHRA and EUCOMED
- Registration with relevant bodies; UK Medical Devices Agency
- Classification of products (and proof of)
- Compliance with the Department of Health and Social Care Master Indemnity Agreement
- Declaration of all MDA / FDA reports / alerts, relating to any products, in use or removed from the market
- Product documentation to include design rationale and surgical techniques
- All relevant academic papers and peer review journal submissions
- Product white papers
- Survivorship data including relevant registry information
- Clinical follow up papers monitoring products
- Sterilisation certification
- Audit records

Suppliers must abide by Beyond Compliance for all new entrants to the market (where relevant).

3.2 DHSC Master Indemnity Agreement (MIA)

The Department of Health & Social Care (DHSC) Master Indemnity Agreement (MIA) is an agreement between Department of Health & Social Care in England and Suppliers that provide equipment free of charge, either on loan or on a permanent basis

Suppliers shall possess a current DHSC Master Indemnity Agreement and maintain registration throughout the life of the Framework.

The following link is included for reference:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH117175

3.2.1 Please note - Loans of any kind CANNOT be made without prior registration with the DHSC Master Indemnity Agreement (MIA).

3.3 New Standards or legislation

Where new or subsequent standards come into force during the period of the Framework, Suppliers shall ensure goods and services supplied under this Framework meet them, where appropriate / applicable. Evidence of compliance to the standards/legislation/directives must be made available on request at any time during the term of the Framework . In the event that sufficient evidence is not supplied CPP LLP reserves the right to suspend the relevant product(s) until such evidence is available.

Any product 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).

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

The awarded Supplier must make CPP LLP aware of any product awarded to the Framework Agreement that is classed by the MHRA as a Medicinal Product.

Standards / Directives / Legislative requirements

Criteria applicable across all product lines where appropriate / applicable

STANDARD / DIRECTIVE / LEGISLATION	TENDER REQUIREMENTS
Medical Devices Directive 93/42/EEC (as amended) All products classed by this Directive as a Medical Device must meet the requirements of the Medical Devices Directive and have their CE marking clearly evident on the product and/or packaging.	Class I • Declaration of Conformity to the Medical Devices Directive 93/42/EEC and a copy of MHRA Registration Letter to be provided with the Tender submission. 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.

BS EN 60601-1:2006+A12:2014 Medical electrical equipment. General requirements for basic safety and essential performance	Self-declaration of Conformity to be provided with the Tender submission (if applicable). Evidence may be requested as part of the tender award process. Where not applicable Provide a statement to confirm that this standard is not applicable to your products. You will need to declare for each product line submitted.
Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC)	Any product that contains phthalates must be indicated on the packaging. Samples of the labelling will be required as a condition of award. This can be in the form of actual samples, artwork or images COSHH safety data sheets for all applicable products must be provided to CPP LLP with the Tender submission.
ISO 17664:2017 Processing of health care products - Sterilisation and disinfection in general.	Specifies requirements for the information to be provided by the medical device manufacturer for the processing of a medical device that requires cleaning followed by disinfection and/or sterilisation to ensure that the device is safe and effective for its intended use.
ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	Specifies requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilised medical devices until the point of use.

3.4 Quality Management System relating to Medical Devices

Manufacturers of equipment provided under this Framework shall possess and maintain registration of ISO13485: 2016 Medical Devices – Quality Management Systems accreditation.
Suppliers shall evidence QMS compliance throughout the term of the Framework.

Distributors / agents etc, who are bidding on behalf of a manufacturer are required to ensure that the manufacturers they are supplying on behalf of, have the necessary quality management systems in place to ensure compliance (and evidence compliance) with this Specification.

Distributors / agents shall possess and maintain registration of ISO 9001:2015 – Quality Management System or an equivalent quality assurance standard.

3.5 Quality Assurance

Suppliers shall evidence QA compliance throughout the term of the Framework.

3.5.1 **Quality Assurance Products**

CPP LLP supports the requirements of the Participating Authorities' Clinical and Product Assurance (CaPA) function which seeks to systematically and consistently apply assurance criteria to each part of the procurement process by providing relevant guidance and tools to measure compliance with the associated assurance requirements.

CaPA are responsible for providing oversight to the procurement process and to assure all associated strategies comply with the CTSP Assurance Guidance ensuring that all procurement decisions are safe, fit for purpose and value for money, and represent the needs of Allied Health and Care Professionals (AHCPs), patients, carers and citizens across the Health and Care System.

CaPA has developed an Assurance Framework which allows a consistent and effective approach to clinical and product assurance to be established.

A single definition of quality in the NHS was first set out in "High Quality Care for All" (2008), following the NHS Next Stage Review led by Lord Darzi. This definition sets out three dimensions to quality, all three of which must be present to provide a high-quality service:

- Outcomes/Clinical effectiveness: quality care is care which is delivered according to the best evidence as to what is clinically effective in improving an individual's health outcomes;
- Safety: quality care is care which is delivered to avoid all avoidable harm and risks to the individual's safety;
- Patient experience: quality care is care which looks to give the individual as positive an experience of receiving and recovering from the care as possible, including being treated according to what that individual wants or needs, and with compassion, dignity and respect". (Quality in the new health system – National Quality Board January 2013)

The underlying principle of the Assurance Process is to continually support the Health and Care system to improve patient safety, service quality and associated health outcomes.

The Assurance Process is aligned with partner organisations (NHS England, NHS Improvement, HealthTech Connect, GIRFT, Accelerated Access Review, Office of Life Sciences), so providing consistent requirements for Suppliers to ensure:

- Products procured are safe, fit for purpose and value for money;
- Patient safety and Supplier compliance with medical device regulations is integral to the assurance process;
- All stakeholders across the health and care system inform product specifications;
- Product evaluations reflect clinical product complexity and dependencies; and
- Special requirements for product storage and/or maintenance are defined within the product specification to minimise additional costs to the Supplier and/or user, due to practices that are not aligned with the manufacturer's recommendations.

3.5.2 **Patient Safety**

Patient Safety concerns raised via the complaints process and/or existing regulatory standards will inform the procurement process working in collaboration with NHS Improvement, NHS England and other partners to implement an 'early warning system' proactively to address any issues raised by AHCPs and/or patient, carers and citizens as a priority.

3.5.3 **Innovation / Health Tech Connect**

HealthTech Connect is a secure online system for identifying and supporting health technologies as they move from inception to adoption in the UK health and care system.

It is intended for devices, diagnostic and digital health technologies that either:

- offer measurable benefits to patients (or other health and care service users) compared to those already offered by current routine practice in the UK, or
- provide measurable benefits to the UK health and care system compared to those already offered by current routine practice in the UK

Suppliers should input information about new products with the potential to offer additional user benefits onto HealthTech Connect. This is a digital system hosted by the National Institute for Health and Care Excellence. The system is secure, recognising the confidential nature of the information held. This information will be viewed by an approved list of national bodies who have specified roles in supporting companies in the development of their products, in evaluating appropriate products and in relevant procurement and commissioning processes. It will also be used by the Accelerated Access Programme in its work to identify and support products with high potential which should be fast tracked to wide scale adoption. Further information can be found here: www.HealthTechConnect.org.uk.

3.5.4 **Product / Asset Management**

3.5.4.1 The Supplier shall have a robust asset management system and thereby maintain a register of serial numbers, date of supply and products which have been supplied to each Participating Authority during the term of the Framework.

3.5.4.2 Suppliers shall furnish NHS Supply Chain with relevant "Field Safety Notices" (FSN) "Safety Action Bulletins" (SAB) and "Medical Device Alerts" (MDA) relating to products provided under this Framework within 3 days of detection / identification of a concern to CPPSupport@supplychain.nhs.uk

3.5.4.3 Suppliers shall notify CPP LLP of any Medical Device / MHRA alerts relating to any products submitted and during the lifetime of the Framework Agreement.

3.5.5 **Product Recall**

3.5.5.1 The Supplier shall ensure that it has robust procedures to respond to any product recall. In the event of products being recalled or defective the Supplier shall, without delay and at its own expense, arrange for the collection and replacement for any product(s) delivered but unused, including part used packs.

3.5.5.2 If the Participating Authority finds that there is no suitable alternative product available within the Supplier's product range to replace the affected product, the Supplier is required to recompense the relevant Participating Authority to the value of the stock uplifted. In these circumstances, the Participating Authority also reserves the right to move its business to another Supplier on the Framework Agreement in order to maintain its service.

3.5.5.3 Where a batch number of a product is identified as being defective, the Supplier shall replace the defective batch(s) with the same product but different batch numbers. The Supplier shall maintain communication with the Participating Authority to confirm dates and times of delivery of replacement products, to ensure no impact of patient care delivery.

3.6 Coding Requirements

The Supplier shall ensure full compliance with any guidance issued by the Department of Health and Social Care in relation to coding requirements.

3.6.1 GS1 Standards

3.6.1.1 GS1 standards are a fundamental part of the Department of Health and Social Care (DHSC) strategy for building a safer and more efficient NHS – standards for barcoding to uniquely identifying places, products and people (patients and staff).

3.6.1.2 All product shall comply with the GS1 coding standard by 30th September 2020.

3.6.1.3 For products / packs too small to carry a linear barcode, a GS1 DataMatrix barcode is to be used.

3.6.1.4 GS1 standards include:

- GTINs (Global Trade Item Number) to identify products
- GLNs (Global Location Number) to identify locations
- GDSN (Global Data Synchronisation Network) to manage product catalogues
- GS1 XML to standardise purchase to pay business messages such as electronic invoices and purchase orders

3.6.1.5 Please note – if not fully compliant by the date indicated in 4.3.2, the Supplier's status on the Framework Agreement will be suspended until such time that the Supplier becomes compliant. Participating Authorities will also be advised to suspend any call-off Contracts.

3.6.2 Other Unique Device Identification Systems (UDI)

The Authority can accommodate other Unique Device Identification Systems – the preference is GS1

3.6.3 PEPPOL

Pan-European Public Procurement Online (PEPPOL) refers to a set of specifications and governance model that focuses on the critical eProcurement components to solve interoperability issues in Europe.

3.6.3.1 This technology facilitates the electronic exchange of purchase orders and invoices.

3.6.3.2 Participating Authorities and Suppliers must select a PEPPOL access point provider.

3.6.3.3 The Supplier shall have the ability to receive purchase orders electronically via the PEPPOL network that contain the GS1 identifiers (GTIN and GLN) and when a purchase order is received from an NHS customer, or party acting on behalf on an NHS customer, via the PEPPOL network, the ability to return an Order Response message via the PEPPOL network to NHS customers.

3.6.4 **Data Security and Protection Toolkit (DSPT Toolkit) - previously The Information governance Toolkit (IG Toolkit)**

3.6.4.1 The NHS's IG (Information Governance) Toolkit was superseded by the DSP (Data Security and Protection) Toolkit in April 2018. A further update to the Data Security and Protection Toolkit Standard (DSPT) has been completed by the NHS for 2019-20. And on June 3rd, the NHS withdrew the previous version. The new Toolkit is live, and Suppliers can no longer publish against the old standard.

3.6.4.2 Compliance with the DSPT Toolkit is mandatory for organisations that access the HSCN (Health and Social Care Network), which replaced N3 in 2017.

3.6.4.3 The deadline for completing the DSPT Toolkit was 31 March 2019, although larger organisations must have completed their submissions by October 2018.

3.6.4.4 The DSP Toolkit requires organisations to demonstrate that they are implementing the ten data security standards set out by the National Data Guardian and the requirements of the EU GDPR (General Data Protection Regulation).

3.6.4.5 Any Supplier providing goods / services to the NHS with access to or/and the storing of and/or transfer of (e.g. patient information) must be DSPT Toolkit accredited to level 2 or better and maintain accreditation throughout the term of the Framework.

3.6.4.6 I.G Toolkit Registration link – https://www.itgovernance.co.uk/ig-toolkit

3.7 Patient Confidentiality

3.7.1 The Supplier shall ensure that all patient information (personal and sensitive) is correctly handled in accordance with the General Data Protection Regulation (GDPR) Regulation (EU) 2016/679

3.7.2 Personal information is any piece of information that relates to a living, identifiable human being. People's names, contact details, financial health, purchase records: anything that you can look at and say "this is about an identifiable person"

3.7.3 Sensitive data encompasses a wide range of information and can include ethnic or racial origin; political opinion; religious or similar beliefs; memberships; physical or mental health details; personal life; or criminal or civil offences. These examples of information are protected by civil rights policies.

3.8 NHS Supply Chain's Ethical Procurement / Code of Conduct

3.8.1 Ethical sourcing is the process of ensuring the products being sourced are obtained in a responsible and sustainable way, that the workers involved in making them are safe and treated fairly and that environmental and social impacts are taken into consideration during the sourcing process.

3.8.2 NHS Supply Chain delivers an end to end logistics and supply service to the English NHS. We are fully aware of the responsibility we bear toward our customers, employees and the communities in which we work. Thus, we have given ourselves a strict set of ethical values to guide us in our business

dealings. We expect all our suppliers, i.e., all companies who do business with NHS Supply Chain, to adhere to the same ethical principles. For this purpose, NHS Supply Chain has drawn up this Supplier Code of Conduct, (See Appendix 14) which sets the standards for doing business with us.

3.8.3 The supplier shall comply with all laws applicable to its business. The supplier should support the principles of the United Nations Global Compact, the UN Universal Declaration of Human Rights as well as the 1998 International Labour Organisation Declaration on Fundamental Principles and Rights at Work, in accordance with national law and practice.

3.8.4 **Modern Slavery Assessment Tool (MSAT)**

3.8.4.1 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.

3.8.4.2 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.

3.8.4.3 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.

3.8.4.4 The MSAT report scoring mechanism is:

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

3.8.4.5 **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.

3.8.4.6 **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.

3.8.4.7 **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.

3.8.4.8 **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.

3.8.5 **Environmental Considerations**

All NHS stakeholders are committed to promoting environmental and sustainability issues within all frameworks and contracts.

3.8.5.1 **Corporate social responsibility (CSR),** also called corporate sustainability, sustainable business, corporate conscience, corporate citizenship or responsible business is a type of international private business self-regulation. A copy of your CSR policy is required for supporting information.

3.8.5.1.1 **Suppliers** shall demonstrate a commitment to incorporate environmental and sustainable considerations into all elements of the Framework including 'Green' transport initiatives, packaging, description of how environmental factors are "taken into account" in respect of manufacturing, material sourcing and ethical trading.

3.8.5.1.2 Suppliers shall identify environmental management awards that have been received, and/or externally recognised programmes to which their company is involved.

3.8.5.1.3 The Supplier shall comply with the requirements of the Packaging (Essential Requirements) Regulations 2015 (as amended) which implements the EU Directive on Packaging and Packaging Waste (94/62/EC) in the UK, and which requires packaging to be minimised, recoverable, and not to exceed by weight specified concentrations of heavy metals.

3.8.5.2 **ISO 14001 or Equivalent**

It is expected that Suppliers effectively manage their environmental performance and minimises negative impact where possible. Suppliers shall hold an Environmental / Sustainability Certificate – ISO 14001 or equivalent in support of their commitment to promoting environmental and sustainability issues. Suppliers shall provide a copy of their Environmental / Sustainability Certificate – ISO 14001 or equivalent.

3.8.5.3 **Packaging Regulations**

The Supplier shall comply with the requirements of the Packaging (Essential Requirements) Regulations 2015 (as amended) which implements the EU Directive on Packaging and Packaging Waste (94/62/EC) in the UK, and which requires packaging to be minimised, recoverable, and not to exceed by weight specified concentrations of heavy metals.

3.8.5.4 **Waste Carriers Licence**

Any business transporting waste, whether their own or someone else's; for free or for profit; must now register as a waste carrier with the Environment Agency in England. The Supplier shall ensure that appropriate registration and a Waste Carriers Licence is available for inspection, should the transporting of waste be applicable at any time under this Framework.

3.8.5.5 **Sustainability**

The Supplier shall support the Authority and the Department of Health and Social Care with the implementation of the voluntary instrument entitled: "Green Public Procurement Criteria for Electrical and Electronic Equipment used in the Healthcare Sector (EU GPP for EEE)" and shall in particular provide upon request the following:

- User instructions for green performance management, including instructions on how to maximise the environmental performance of the Goods;
- Training with energy efficiency optimisation, including on the adjustment and finetuning of the Goods in relation to their consumption of electricity (using parameters (for example, standby mode) in order to optimise the electricity use);
- Installation with energy efficiency optimisation, and a 'needs assessment' for the Participating Authority so the Participating Authority understands how to optimise the Goods' electricity consumption;
- Confirmation of the energy profiles of the Goods (where pre-determined use scenarios exist within EU GPP Guidance).

For Goods with no pre-determined use scenarios, the Authority may develop these during the term of the Framework Agreement.

3.8.5.6 **Management and disposal of healthcare waste (HTM 07-01)**

Upon request - The Supplier shall provide information on the management of the product at end-of-life, including (but not restricted to) opportunities for re-use and recycling.

Product literature shall identify information pertaining to the disposal; re-use; refurbishing or recycling of products.

3.8.5.7 **Re-useable Medical Devices**

Manufacturer's instructions shall be provided regarding re-useable medical devices to facilitate decontamination between each episode of use.

3.8.5.8 **Single Use Medical Devices**

Do not reuse. A single-use device is used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

All single use devices shall display the Medicines and Healthcare Products Regulatory Agency (MHRA) symbol on the packaging or the device.

3.8.5.9 **Single Patient Use Medical Devices**

Single-patient use means the medical device may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use.

3.8.5.10 **Limited use instruments**

The medical device is intended only for a specified number of uses. It is therefore required that the number of uses is recorded and that the item is discarded after being used for the maximum recommended number of times.

3.9 Product Specific Requirements

Section 3.9 details the scope of the products for each of the six Lots

3.9.1 **LOT 1 – Clips and Clip Appliers**

3.9.1.1 Ligation products must be designed for marking or ligating tissue structures.
3.9.1.2 Laparoscopic products must fit into standard trocar diameters and be between 200mm and 450mm in length (+/- 10%) to accommodate paediatric, adult and bariatric sizes.
3.9.1.3 Products must display if sterile or provide instructions on how to sterilise.
3.9.1.4 Where products are disposable this must use established waste streams within the clinical settings.
3.9.1.5 Must be DEHP Free
3.9.1.6 Must display the size of the clip on the individual packet.
3.9.1.7 Must be able to differentiate between the different sizes of the appliers and allocate the correct clip size to its relevant applier.
3.9.1.8 Clip appliers must have 360 degrees of rotation of the tip independent of the handle.
3.9.1.9 Products provided sterile must have a minimum of 2 years shelf life.

3.9.1.10 Ligation clips:

- Can be absorbable or non-absorbable;
- Must be made from MRI compatible materials
- Clip size must be indicated on packaging

3.9.1.11 Ligation products will include one of the following;

- Ligation clip applier
- Pre-loaded ligation clip applier
- Ligation clips

3.9.2 **LOT 2 – Energy Based Devices**

3.9.2.1 These devices utilise one or more of the following, Ultrasonic, Advanced bipolar or Bipolar energies as their primary function in order to dissect tissues, blood vessels etc. more recently devices have been launched into the market that have several forms of energy in one system. Advanced products may use tissue impedance changes to modify the energy levels and waves, this tries to reduce collateral tissue damage and prevent charring of the tissues which can lead to later bleeding occurring.

3.9.2.2 These products may contain reusable, single patient and/or remanufactured parts.

3.9.2.3 These products can be reusable, remanufactured or single patient.

3.9.2.4 Remanufactured products must provide clear instructions on how to clean products prior to storage and awaiting collection. Provide appropriate storage equipment and guidance of suitable products to clean these products.

3.9.2.5 Used remanufactured products must provide a process for collection of cleaned products in a timely manner to prevent the build-up of used and contaminated products being stored.

3.9.2.6 Remanufactured products must have full traceability in place and a process in place to escalate any recalls or updates.

3.9.2.7 Products must be latex free/DEHP free.

3.9.2.8 Where products are delivered sterile, they must have at least a 2-year shelf life.

3.9.2.9 Products must display if sterile or provide instructions on how to sterilise.

3.9.2.10 Where products are disposable this must use established waste streams within the clinical setting.

3.9.2.11 Energy products will include:

- Advanced bipolar energy devices
- Bipolar energy devices
- Ultrasonic energy devices
- A combination of any of these devices above
- Accessories specific to the energy products listed above

3.9.2.12 The following needs to be applicable and stated,

- Jaw size under 20mm
- Jaw size over 20mm
- Jaw shape straight
- Jaw shape curved

3.9.3 **LOT 3 – Surgical Stapling Devices**

3.9.3.1 The purpose of these devices is to staple or seal tissues, some may also cut these tissues. Staplers consist of a device to apply staples, the staples and may also include a blade or device to cut.

3.9.3.2 Powered stapling will include as a minimum, a single use or reusable stapler that is supplied either preloaded with staples or unloaded to allow the user to load staples and utilise a power source to close the device.

Stapling products include:

3.9.3.3 Linear stapler cutter - comprising of either a single patient device or a reusable stapler and staple loading unit complete with staples. A linear cutter must have the ability to perform straight cuts and close tissue with staples.

3.9.3.4 Linear stapler - must be able to close tissue with staples and be available in following configurations:

- Reusable or single use reloadable stapler and separate staple packs
- Single use pre-loaded stapler
- Separate staple loading unit
- Circular stapler - used to close tissue with staples in a circular formation (e.g. for forming an anastomosis), required as a single patient use pre-loaded or reloadable stapler, disposable or reusable.
- Haemorrhoid staplers - circular for haemorrhoid stapling and required as a single patient use or reusable, pre-loaded or reloadable stapler;
- Laparoscopic staplers – able to cut and staple specifically for laparoscopic surgery comprising single use or reusable stapler and single use loading unit;
- Powered stapling devices are typically powered by batteries,
- NB. unless using a reusable rechargeable battery consideration needs to be considered for environmental impact of the waste this generates.
- Stapler accessories specific to the stapling devices (handle, battery covers etc.)
- Where products are delivered sterile, they must have at least a 2-year shelf life.
- Products must display if sterile or provide instructions on how to sterilise.
- Where products are disposable this must use established waste streams within the clinical setting.
- Products must be latex free
- Products must be DEHP free

3.9.4 **LOT 4 - Laparoscopic Instruments**

3.9.4.1 Instruments designed for minimally invasive laparoscopic procedure; instruments must be suitable for use through a port or trocar. Consideration needs to be given for paediatric, standard and bariatric patients

3.9.4.2 Laparoscopic instruments include but shall not be limited to:

- Laparoscopic Instrument Tips
- Laparoscopic Shafts
- Laparoscopic Inserts
- Laparoscopic Non-Ratchet Handles
- Laparoscopic Ratchet Handles
- Non-Toothed Graspers
- Toothed Graspers
- Fenestrated Graspers
- Curved Graspers
- Laparoscopic dissectors
- Laparoscopic monopolar forceps, graspers and dissectors
- Laparoscopic needle holders
- Uterine manipulator –uterine control during laparoscopic procedures
- Laparoscopic scissors – used to cut across tissue or sutures
- Single patient use and reusable retractors suitable for minimally invasive surgery
- Laparoscopic suction/Irrigation Sets and Adapters

- Laparoscopic morcellator - used for the division and removal of large masses of tissues during laparoscopic surgery
- Retrieval Bags
- Laparoscopic Retrieval Bags
- Laparoscopic Retractors
- Wound Retractors
- Laparoscopic Instrument Accessories
- Blunt Dissecting Instruments, hook, spatula etc.
- Laparoscopic swab on stick
- Bowel sizer

3.9.5 **LOT 5 - Trocars**

3.9.5.1 A trocar is a medical device that is made up of an obturator, and a cannula. Trocars are placed through the abdomen during laparoscopic surgery. A trocar is a combination of an obturator and a cannula. There are number of types of trocars including Bladed, Blunt Tip, Bladeless etc. Insufflation tubing, smoke extraction etc are connected to these trocars through a luer type tap. These can be single patient use or reusable.

3.9.5.2 This Lot includes the following:

Trocars with one the following diameter sizes stated,

- 3mm
- 5mm
- 8mm
- 10mm
- 11mm
- 12mm
- 15mm
- Greater than 16mm

Cannulas with one the following diameter sizes stated:

- 3mm
- 5mm
- 8mm
- 10mm
- 11mm
- 12mm
- 15mm
- Greater than 16mm

Obturators:

- 3mm
- 5mm
- 8mm
- 10mm
- 11mm
- 12mm
- 15mm
- Greater than 16mm

3.9.5.3 Additional Product Areas:

- Scope warmer products
- Anti-Fog products
- Insufflation tubing
- Veress needle
- Laparoscopic suturing closure devices
- Smoke Evacuation Filters and Attachments specific to Trocars
- Trocar Accessories
- Multi Ports

3.9.6 **LOT 6 – Abnormal Uterine Bleeding Systems**

3.9.6.1 Products designed for and used to address conditions of the uterus and abnormal uterine bleeding including but not limited to:

- Endometrial Ablation; and
- Fibroid/polypectomy.

3.9.6.2 Hysteroscopes must be designed to enable visualisation of the inside of the uterus (hysteroscopy) to aid diagnosis in cases including:

- Menorrhagia or irregular periods;
- Bleeding between normal periods, after sexual intercourse or after Menopause;
- Pelvic pain;
- Unusual vaginal discharge;
- Repeated miscarriage; and
- Infertility.

3.9.6.3 Endometrial ablation products must be designed for the treatment, removal or destruction of the endometrium (lining of the uterus) for women with heavy uterine bleeding and to enable the NHS end user to comply with NICE Guidelines for endometrial ablation.

3.9.6.4 Techniques used to address uterine bleeding include but shall not be limited to the following (including their power source/generator):

- Microwave endometrial ablation – using microwave energy to heat and destroy the endometrial lining;
- Hydrotherm ablation/Saline – comprising a probe with a scope for viewing the lining of the uterus whilst heated saline is introduced and circulated to destroy the lining of the uterus;
- Thermal ablation – a laser is used to ablate the lining of the uterus;
- Radiofrequency – impedance controlled bipolar radiofrequency ablation using radiofrequency energy to heat and destroy the endometrial lining; and
- Cryotherapy – comprising a probe cooled to sub-zero temperatures placed into the uterus under ultrasound guidance. The cold temperature removes the inner lining of the uterus.

3.9.6.5 Products used to address abnormal uterine bleeding include but shall not be limited to:

- Microwave ablation devices;

- Bipolar radio frequency devices;
- Heated balloon/saline device;
- Thermal ablation device; and
- Power source or generator.

3.9.6.6 Fibroid/polypectomy products - products used during a hysteroscopy to remove abnormal growths and tissue from the womb including but not limited to:

- Fibroids – non-cancerous growths that can develop inside the womb and can sometimes cause symptoms such as pain and heavy periods;
- Polyps – small growths that develop on the lining of the womb and can cause irregular and heavy periods;
- Intrauterine adhesions – sections of scar tissue that can cause absent periods and infertility; and
- Thickening of the uterus' lining (endometrial hyperplasia).

3.9.6.7 Fibroid/polypectomy products shall include but not be limited to:

- Hysteroscopic Myomectomy / Fibroid / polypectomy products (specifically for the removal of intrauterine pathology and the treatment of myomas and polyps);
- Vacuum source;
- Electro cutter blade;
- Hysteroscopic morcellator;
- Hysteroscopic fluid management system;
- Hysteroscopic bipolar electrodes;
- Bipolar generator or power source;
- Hysteroscopes used specifically in conjunction with the device;
- Hysteroscopic forceps;
- Hysteroscopic graspers; and
- Hysteroscopic polyp snares.

3.9.6.8 Products designed for and used to address conditions of the uterus and abnormal uterine bleeding including but not limited to:

- Endometrial Ablation; and
- Fibroid/polypectomy

3.9.6.9 Hysteroscopes must be designed to enable visualisation of the inside of the uterus (hysteroscopy) to aid diagnosis in cases including:

- Menorrhagia or irregular periods;
- Bleeding between normal periods, after sexual intercourse or after Menopause;
- Pelvic pain;
- Unusual vaginal discharge;
- Repeated miscarriage; and
- Infertility.

3.10 Packaging

3.10.1 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

3.10.2 All sterile packed products must be handled and sealed in compliance with ISO 11607-1:2019 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.

3.10.3 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.

3.11 Product Trials/Evaluations

3.11.1 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.

3.11.2 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.

3.11.3 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.

3.11.4 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.

3.11.5 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.

3.11.6 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.

3.11.7 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.

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

3.12 Product Changes Throughout the Framework

3.12.1 New Products / Range Extensions

3.12.1.1 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.

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

3.12.1.3 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.

3.12.1.4 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.

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

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

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

3.12.1.8 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.

3.12.2 **Product changes**

3.12.2.1 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.

3.12.2.2 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.

3.12.2.3 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

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

3.12.3 **Product obsolescence – Delisting**

3.12.3.1 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

3.12.3.2 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.

3.12.3.3 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.

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

3.12.3.5 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.

3.12.3.6 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".

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

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

3.13 Business Continuity

3.13.1 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

3.13.2 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

3.13.3 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).

3.13.4 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.

3.14 Brexit

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

3.14.2 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

3.14.3 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.

3.15 Account Management

3.15.1.1 There is a requirement for the Supplier to provide a range of activities in support of the Framework Agreement, including but not limited to:

- new accounts when new business is awarded
- implementation / exit plans
- clinical training and training of any affected member of staff, if required
- new product launches / phasing out of technology – swap outs
- on site customer engagement
- technical and professional support available as and when required

3.15.1.2 Suppliers are expected to maintain routine communication with each Participating Authority through a relevant account manager and clinical lead.

3.15.1.3 Supplier Representatives shall be a named contact designated for Account Management support and be contactable during normal working hours. An out of hours contact should be available as may be required and alternative nominated persons should be identified and contact information supplied, should the main representative contact not be available.

3.15.2 **Customer Services**

3.15.2.1 The Supplier shall provide a responsive customer service function during normal working hours which enables a customer to resolve issues, over the telephone or by e-mail, within a maximum 24-hour timescale.

3.15.2.2 Individual Participating Authority accounts shall have a named Supplier Specialist Support Staff / Sales Representative with customer facing responsibilities. Key roles and responsibilities and how they will interface with the Participating Authority shall be provided and maintained.

3.15.3 **Compliments and Complaints**

3.15.3.1 The Supplier must have a clear and comprehensive written complaints management procedure. This procedure will be followed in the event of any issue to the supply of goods or support provided as part of the Framework Agreement. Such procedure shall enable CPP LLP Customer Services or the Participating Authority to make complaints quickly and simply and shall require the Supplier to investigate and resolve a complaint in accordance with strict timescales. For the avoidance of doubt complaints can be written or verbal.

3.15.3.2 The Supplier shall keep a full written record of the nature of each complaint and details of the action taken as a result of the complaint. Records shall be available for inspection at any time. This is to show:

- Reason for the complaint, from whom and date
- Initial complaint, complainant, Participating Authority and date
- Action taken
- Corrective Action taken to prevent recurrence (complaint)
- Date of resolution

3.15.3.3 The Supplier shall use reasonable endeavours to ensure that all complaints are resolved within 10 days of the complaint being notified to the Supplier, unless the nature of the complaint requires additional investigation or action, in which case the Supplier shall ensure that the complaint is resolved as soon as possible thereafter. Where the complaint relates to a faulty or spoiled device or product the Supplier shall provide a full written report, with supporting root cause analysis to the relevant Participating Authority within one month of the complaint.

3.15.3.4 The details of how the complaint has been resolved should be notified to CPP LLP Customer Services in writing as soon as possible thereafter and the Supplier will on request at any time provide CPP LLP Customer Services with an update as to the progress of the resolution of the complaint. It is a requirement that Suppliers have corrective/preventative action plans in place to remove the causes of an existing or potential undesirable situation.

3.15.3.5 The Supplier shall possess a complaints policy which details roles and responsibilities of key roles and details escalation routes. A copy of which should be provided as part of the Tender submission.

3.15.4 **Company Representatives On-Site Conduct Visiting NHS Sites**

3.15.4.1 Supplier Representatives must comply and ensure that its staff comply with the requirements of the Health and Safety at Work Act 1974 and other relevant legislation, including regulations and codes of practice issued there under and with the Participating Authority's own policies and procedures.

3.15.4.2 The Supplier shall ensure that all staff assigned to the call-off Contract shall possess, and exercise relevant care, appropriate qualifications, expertise and experience as are necessary for the proper provision of support. Supplier staff must at all times when on Participating Authority premises, wear an identification badge, complete with photograph.

3.15.4.3 The Supplier's representative shall meet with the Participating Authority staff only by prior appointment. Product presentations and samples should only be provided to wards or medical and / or nursing staff following discussion and agreement with the Participating Authority employed clinical lead or a member of their team to do so.

3.15.4.4 When the attendance of an appointment cannot be met, the Supplier Representative shall withdraw the meeting request giving as much notice as possible.

3.15.4.5 Supplier Representatives promoting the sale of their products and services shall not enter any clinical or non-clinical area without an appointment unless otherwise advised by the Participating Authority(s).

3.15.4.6 A Representative who does not have a pre-arranged appointment may be asked to leave the premises.

3.15.4.7 Representatives arriving for an appointment (pre-arranged time and place) shall be met by the person with whom they have an arrangement; or a person designated by them.

3.15.5 **Technical and Professional Support**

3.15.5.1 The Supplier is required to have capacity and ability to provide on-site technical support throughout the country when requested by clinical staff or CPP LLP staff. This requirement will be specific to each individual Participating Authorities support requirement and will be identified and agreed during implementation or anytime throughout the term of the Framework.

3.15.5.2 Supplier product specialist support staff shall have the technical capabilities (training & experience) to undertake in depth discussions with Participating Authority clinical staff and CPP LLP and/or Authority staff, to support clinical discussions and when requested conduct on-site training.

3.15.5.3 Clinical procedure support shall be required pre, during and post procedures by the Supplier's Specialist Product Support Staff / account manager / relevant knowledgeable team member.

3.15.6 **Supplier Product Specialist Support Staff**

3.15.6.1 Supplier Product Specialist Support Staff training, qualifications / competency records shall be available to assure the confidence of clinicians.

3.15.6.2 Supplier Product Specialist Support Staff shall be required to evidence the effectiveness and customer satisfaction rating of their: -

- training sessions
- implementations (planning & deployment)
- product trials
- product / systems knowledge
- ongoing support

3.15.6.3 Training programmes must be fit for purpose, competency based wherever possible and appropriate to the products provided. Training shall be supplied free of charge, at Participating Authority sites or "as agreed" and repeated when staff changes necessitate.

3.15.6.4 Training and education programmes should be available to all levels of clinical staff, including Nurses, ODP, Surgeons and Registrars. Programmes should support an individual's Continuous Professional Development with either certificates provided, or points awarded for technique focused courses.

3.15.6.5 Product Training Programmes shall provide individuals with the knowledge and skills they need to identify:-

- Selection and appropriate use of the products
- Risk assessment for patients

3.15.7 **Theatres**

3.15.7.1 Supplier's relevant representatives may gain access to Theatres, to provide technical assistance during a surgical procedure, to observe, demonstrate, in service or commission new equipment or products during a surgical procedure.

3.15.7.2 Supplier's relevant representatives shall be observant of individual Participating Authority policies and procedures regarding access to clinical areas e.g. theatres and secure areas.

3.15.7.3 Policies and requirements for access to clinical areas may include but not be limited to: -

- Qualifications / Training e.g. theatre access course
- Vaccination records
- Disclosure and Barring Service (DBS) standard / enhanced check
- Photo identity
- Supplier introduction
- Theatre attire
- Visit supervision
- Policies, procedures, protocols
- Access to staff rest areas
- Action to be taken if you feel unwell

3.15.7.4 Access and working practices shall always be strictly observed and adhered to.

3.15.7.5 Non-compliance to site protocols shall result in the Supplier's representative being asked to leave immediately, and an account / report provided to their employer.

3.15.8 **Secure Areas**

3.15.8.1 Supplier Representatives who require access to consignment stock to audit or for other purposes shall hold a current DBS check, carry photo identity and notify a nominated person in advance of their requirement for access.

3.15.9 **Training**

3.15.9.1 Suppliers shall provide training programmes relating to their products and services for Theatre staff, Sterile Services and Consultants covering everything from instrumentation recognition and maintenance to surgical techniques.

3.15.9.2 Supplier staff providing training in a clinical area shall adhere to Participating Authority policies and procedures and evidence their enhanced DBS (theatre access training and vaccination record may be applicable).

3.15.9.3 The basic training programme shall be supplied free of charge at Participating Authority sites or "as agreed" and repeated when staff changes necessitate.

3.15.10 **Basic training programme** shall assure: -

- Competency based training – skills and knowledge required to perform specific or a range of tasks in a clinically safe manner.

- Role based training to provide individuals with the knowledge and skills they need to perform their specific roles:

  - familiarity with the systems in use.

  - appropriate use of the products and systems

  - planning – pre-op, post-op, contingencies

  - how to respond to emergencies or breakdowns

- Location of digitally based product literature – pdf / website.
- For all clinical staff, statement of attainment or certificate identifying level of attainment / competency.
- Risk assessment on an individuals' capacity / capability to perform at the required level shall be reported to the named Responsible Person.

3.15.11 **Training for Surgeons / Consultants and Theatre Support Staff**

Suppliers shall offer specific training for Consultants, Surgeons and Theatre Support Staff above "basic training" and at a level appropriate to their skill set. Course details, costs and access details shall be made available to Participating Authorities.

Statistical data in support of effective training outcomes shall be made available to Consultants and CPP LLP on request.

3.15.12 **Product Training**

3.15.12.1 Is required to support and educate clinical staff and other staff groups on the products and services contained within the Framework Agreement.

3.16 Framework Contract Management / Monitoring

3.16.1 Management Information

The Supplier shall provide information to enable performance and ongoing monitoring of the Framework to CPP LLP as detailed below:

3.16.2 Future Opportunities

3.16.2.1 Suppliers will respond to benchmarking requests, approved by Participating Authorities, within 7 working days of the request. This will cover the previous 12 months' activity data for specified Participating Authorities.

3.16.2.2 The output from benchmarking is for CPP LLP to provide the Participating Authority procurement staff, operational teams and clinician(s) with an analysis of the opportunity detailing any cost efficiencies or cost pressures, this information facilitates decision making and determines "next steps" and the development of agreed work plans.

3.16.2.3 It is the responsibility of the Supplier to ensure that the CPP LLP Category Manager is informed of any discussions with a Participating Authority that may directly or indirectly lead to a change in practice or price of the products under the call-off Contract and/or Framework Agreement.

3.16.3 KPI's

3.16.3.1 The KPI's (See Schedule 8 of the Framework Agreement) shall inform the effectiveness of the Framework Agreement between the Supplier, end users and CPP LLP and form part of the contract review meeting discussions with the CPP LLP Tower 2 Category Team.

3.16.3.2 CPP LLP reserve the right to include additional KPI measures during the term of the Framework Agreement as circumstances may dictate.

3.16.4 Contract Review Meetings

3.16.4.1 Suppliers are expected to meet with the CPP LLP Tower 2 Minimally Invasive Surgery Category Team at least every quarter for the purpose of reviewing the Supplier's performance. Such meetings must be attended by the relevant account manager from the Supplier. Meetings may increase to monthly as may be required depending on the nature of the call-off Contract/ access agreement in place.

3.16.4.2 Representatives from the individual Participating Authorities may also require similar meetings on a quarterly basis as part of their own call-off Contract with the Supplier. The Participating Authority will agree these requirements with the Supplier on a case by case basis.

3.16.4.3 As a minimum, the review meetings will include the following items for discussion:

- review of any new opportunities/implementation/transitions;
- out of stock/non-delivery report;
- new products/innovations;
- key Performance Indicators (KPI's);
- product and Service developments; and

- complaints/Compliments and feedback.

3.16.5 **Contract Implementation for New Customers**

3.16.5.1 On the award of any new business, if requested by the Participating Authority, the Supplier is expected to provide a detailed implementation plan to support the switch of product from the Participating Authority's incumbent supplier. It is expected the implementation plan includes the following key points to ensure that there is minimal disruption to services during and after transition:

- Supplier resource provided to support any transition
- Define and agree delivery lead time expectations
- Identify key end users
- Initial training plan for appropriate product usage
- Supporting literature distribution
- Agree the support required (clinical and technical)
- Identification of any resource intensive tasks required during implementation

3.16.5.2 Contract implementation meetings shall be held with the Supplier to facilitate the resolution of any "teething problems" and establish an understanding of working relationships as part of call off Contracts under the Framework Agreement.

3.16.6 **Orders for Participating Authority Requirements**

3.16.6.1 Transacted sales – edirect. Please see Appendix 13 which details the operating process for eDirect services with the Authority. The Supplier must comply with the operating process detailed in Appendix 13 to facilitate the e Direct ordering services.

3.16.6.2 eDirect relates to goods and services ordered by the Authority on behalf of the Participating Authority which are delivered direct to the Participating Authority and invoiced to the Authority.

3.16.6.3 The Authority has an ordering system which is used by most Participating Authorities to issue purchase orders for direct delivery to their stores or clinical area. The Authority can create standing orders for customers who require a regular delivery of the same products and quantities – a unique purchase order number will be created for each order / delivery.

3.16.6.4 A call-off order will be placed by each Participating Authority based on their anticipated individual annual usage/spend. They will use this order to purchase volumes as and when required. The Supplier is required to send only the quantity released from the call-off order.

Or: - Alternatively Participating Authorities will place ad-hoc orders as and when a requirement is identified for direct delivery.

Or: - Products will be ordered via third party vendors and retrospective quarterly discounts should be made payable direct to the individual Participating Authority within 14 days of the end of each quarter. Any such discount should be clearly identified within the returned Tender submission documents.

Or: - The Authority, CPP LLP with the Participating Authorities' approval, reserves the right to use a 3rd party distribution service, where possible. CPP LLP will work together with the Supplier to make this happen.

3.16.6.5 All 3rd party carriers engaged to deliver goods shall be deemed to be an agent of the Supplier, and not the Customer of the Authority and/or CPP LLP, and the Supplier shall ensure that any agent or sub-contractor engaged by it in the performance of this contract shall comply with the Supplier's obligations under the Framework Agreement.

3.16.6.6 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./European 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.

3.16.7 **Unique Reference Number (URN)**

3.16.7.1 The Unique Reference Number (URN) is issued by the CPP LLP for Participating Authorities that wish to place orders directly with Suppliers. The URN identifies that the Participating Authority is purchasing via the Framework Agreement.

3.16.7.2 Any Supplier quotations provided direct to Participating Authorities shall include the Framework Agreement reference number.

3.16.7.3 Suppliers shall ensure that they have received an URN from CPP LLP prior to delivering goods and services to Participating Authorities under the Framework Agreement.

3.16.8 **Goods Received notes**

The process for goods receipting relating to the edirect system is detailed within the Operational Guide included within **Appendix 13** Supply Chain Operational Guide.

3.16.9 **Invoicing**

The Supplier shall submit invoices which must relate to specific order numbers, either direct to the Participating Authority or to a 3rd party (as advised by each Participating Authority). No personally identifiable data shall be included on invoices or credit notes – this includes any patients' name, NHS number or address.

3.16.10 **Invoice**

Invoices in relation to goods should include as a minimum:

- the order number;
- the name and address of the delivery location (including the requisition point, if appropriate);
- the description and quantity of the Goods as set out in the Order;
- details of any item forming part of the relevant delivery;
- whether any containers supplied are required to be returned or collected; and
- the GTIN (GS1 Code) for the Goods;

Invoices in relation to Services should include as a minimum:

- the name and address of the service recipient; and
- a description of the Services.

3.16.11 **Shared Business Services (SBS)**

Shared Business Services provides some NHS organisations with purchase to pay services. When advised that the Authority or Participating Authority is using SBS, Suppliers shall ensure that they follow the good invoicing practice to reduce invoice rejection.

https://www.sbs.nhs.uk/Supplier-good-invoicing-practice

SBS utilise an e-Invoicing platform through technology partners, Tradeshift

visit **http://tradeshift.com/Supplier/nhs-sbs** for more information

3.16.12 **Order and Invoice Queries**

The Supplier shall contact the purchase order issuing organisation with queries relating to receipt of order and price queries.

3.16.13 **Distributor changes within Lots**

CPP LLP is aware that during the lifetime of the Framework Agreement, a manufacturer of products may decide to change who it utilises to distribute its products. This may be to a distributor who is not listed on the Framework Agreement. Therefore, to ensure the continued availability of that specific manufacturer's particular product, CPP LLP's intention is that any new distributor of that manufacturer's product will be permitted to join the Framework Agreement, provided that any new distributor firstly meets the Selection Questionnaire requirements set out in this ITT.

Any new distributor must abide by the Specification and commercial requirements agreed within the scope of the Framework Agreement and any existing call off Contracts in place with Participating Authorities at the time of change of distributor.