**Schedule A2 (A)**

**PRODUCT SPECIFICATION**

**Medical Examination Gloves & Surgical Gloves**

1. **Introduction**

The Collaborative Procurement Partnership (CPP LLP) on behalf of The Authority is seeking to establish a multi supplier framework agreement for Examination and Surgical Gloves which will provide a comprehensive range of products suitable for use across the NHS in England. The scope of this agreement will include examination gloves (nitrile, latex, vinyl, other specialist examination gloves) Surgical gloves (natural latex rubber, synthetic latex free)

* 1. The Framework is for the following Lots:

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| **Lot Number** | **Lot Title** |
| 1 | Medical Examination Gloves |
| 2 | Surgical Gloves |
| 3 | Nitrile Non-Sterile 6 Newton Medical Examination Gloves |

The purpose of The **Medical Examination Gloves and Surgical Gloves 2021** 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 a Nationally Contracted Pricing Matrix - 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;
* To enable the reopening of competition to support the Nationally Contracted Products model.
* 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.

1.2 Full technical specifications of the products awarded to this Framework Agreement must be made available to NHS Supply Chain on request during the lifetime of this Agreement.

* NHS Supply Chain must be notified immediately about any proposed changes to the technical specifications throughout the lifetime of the Framework Agreement.
* If changes to the technical specification of any offered product mean that the product no longer meets the minimum requirements outlined in this document, NHS Supply Chain reserves the right to exclude the product from the Framework Agreement.
* NHS Supply Chain reserves the right to request evidence of compliance with the specifications outlined in this document throughout the lifetime of this Framework Agreement.
  1. The specifications refer to several 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. Products 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. Evidence of compliance to the standards/legislation/directives must be available to NHS Supply Chain on request during the lifetime of this Agreement; if sufficient evidence is not supplied, NHS Supply Chain reserve the right to suspend product until such evidence is available.
  2. Gloves may meet the definition of both PPE and a Medical Device. These products will be considered to have a dual purpose and will fall within the scope of both the PPE regulation and the Medical Device Regulation.
  3. All products classified as PPE or Dual Purpose must be certified by a UK Approved Body (EU Notified body). Appropriate certification must be supplied e.g. Module B and Module C2/Module D.
  4. All products classified as PPE or Dual Purpose must have UKCA/CE marking followed by the UK approved body/notified body number. All new products to market from 1st January 2021 MUST have UKCA marking, (UKCA marking is required from 1st July 2023 for all products being placed on the UK market under MHRA- Medical Devices and 1st January 2022 for PPE).
  5. **Biocompatibility Compliance** an Evaluation Summary to confirm the biological suitability of the product, must contain the details of the individual who analysed the results and authored the Summary.

1. **Criteria applicable across all product lines**

**Standards and Legislation**

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| **STANDARD / CERTIFICATION** |
| All products must have their **CE/UKCA** marking clearly evident on the product, and/or packaging and must conform to the relevant directive: (UKCA marking is required from 1st July 2023 for all products being placed on the UK market);  **Medical Devices Regulation 2017/745**  Any product that contains phthalates must be indicated on the packaging in accordance with:  **Medical Devices Regulation 2017/745.**  **Personal Protective Equipment Directive (EU 2016/425)**  **EU MDD 93/42/EEC**  **EU PPE 89/686/EEC**  **MDR 2002 or UK PPE 2016** |

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| Medical devices are classified depending on their use and are risk based: | |  |
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| **Product** | **Classification** | **Level of Risk** |
| Non-sterile medical examination gloves | Class I | Low |
| Sterile medical examination gloves | Class Is (sterile) / Class Im (measuring) | Low – Medium |
| Surgical gloves | Class IIa | Low – Medium |

2.1 In accordance with the Control of Substances Hazardous to Health Regulations 2002 (as amended) safety data sheets for all products that fall under this Regulation must be provided to NHS Supply Chain.

2.2. All products and packaging must be **latex free** where possible. Any products or packaging containing latex must be clearly labelled as such to inform the user.  EN ISO 15223-1:2012 symbol for latex

2.3. All products must be supplied with a minimum 3 years shelf life from the date of manufacture.

* 1. Labelling – Must specify the size of the glove and must have a manufacturing and/or expiry date on the packaging.
  2. The sterilisation process for the supply of sterile product lines must be certified by a UK Approved Body (EU notified body).
  3. Where applicable all products must be supplied with instructions for use and disposal/recycling instructions or symbols printed in English.

1. **Products** 
   1. **LOT 1 – MEDICAL EXAMINATION GLOVES** is for the supply of examination gloves made from nitrile, vinyl, latex, or any other suitable material and can be non-sterile or sterile.
   2. The scope of Lot 1 is for Medical Examination gloves intended for use in a wide range of medical and surgical applications
   3. All product lines in this Lot are intended to be disposed of after use and must be clearly marked as such on the primary packaging to inform the user; they are not intended for sterilisation.
   4. Must be a minimum of:

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|  | **Gloves made of Rubbers** *(e.g. Latex)* | **Gloves made of Thermoplastics** *(e.g. Vinyl)* |
| Force at Break (Newtons) | ≥ 6.0 | ≥ 3.6 |

* 1. Where non-latex product is provided, product and packaging must be latex free and clearly stated.
  2. Sterile examination gloves must be sterilised and packed in a way to enable the gloves to remain sterile and the wearer to adhere to ANTT when donned.
  3. Sterile examination gloves must be supplied in pairs individually enveloped within a wallet.
  4. All products must be powder free e.g. Removable Surface Powder: <=2mg/glove.
  5. All products must have a shelf life of at least 3 years from date of manufacture and a minimum of 2 years on delivery into NHS Supply Chain.
  6. The inner glove box should fit neatly into a standard size glove dispensing unit, where applicable.

**4 LOT 2 – STERILE SURGICAL GLOVES** is for the supply of surgical gloves made from natural latex rubber and synthetic latex free.

4.1 Where non-latex product is provided, product and packaging must be latex free and clearly stated.

* 1. Must be a minimum of 9 newton.
  2. To be supplied in left/right hand pairs individually packed
  3. Must be labelled STERILE along with the method of sterilisation and clearly marked sterile on the packaging.
  4. All surgical gloves must be sterilised and packed in a way to enable the gloves to remain sterile and the wearer to adhere to ANTT when donned.
  5. All products must be powder free e.g. Removable Surface Powder: <=2mg/glove

4.7 All products must have a shelf life of at least 3 years from date of manufacture and a minimum of 2 years on delivery into NHS Supply Chain.

**5 Lot 3 6N NITRILE EXAMINATION GLOVES** is for the supply of examination gloves made from 6N nitrile

* 1. Gloves must be a minimum of 6 newton tensile strength.
  2. All gloves and packaging must be latex free and be labelled accordingly.
  3. Glove must have a beaded cuff.
  4. Gloves must have textured fingers.
  5. Gloves must have evidence of chemotherapy drug testing i.e. EN374 and/or ASTM D6978.
  6. Gloves must have independent testing against Bacterial Viral and Fungal penetration i.e. EN374-5 and/or ASTM F1671.
  7. Gloves should be boxed in average quantity of 200 (180 maybe acceptable for XL).
  8. Glove should dispense singularly to minimise wastage.
  9. Supplier must be able to provide all 5 sizes, xs, s, m, l and xl.
  10. All products must be powder free e.g. Removable Surface Powder: <=2mg/glove.
  11. All products must have a shelf life of at least 3 years from date of manufacture and a minimum of 2 years on delivery into NHS Supply Chain.
  12. The inner glove box should fit neatly into a variety of glove dispensing units used in the NHS.
  13. Packaging must be made from 100% cardboard and be 100% recyclable without the need to separate component parts and labelled accordingly.

1. **Latex Related Conditions**
   1. If applicable the Supplier shall ensure that products are free from natural rubber latex in their construction and have not been exposed to latex at any time during manufacturing or packaging procedures.
2. **Storage** 
   1. The Supplier shall identify any special instructions for storage.
3. **Product Technical Information**
   1. The Supplier shall provide the Authority/CPP LLP with technical product information.
4. **Product Evaluations**
   1. Participating Authorities reserve the right to undertake trials and evaluations of alternative suppliers’ products. Any trials and evaluations conducted will be following the individual Authority’s policies and protocols.
   2. Suppliers may provide the Participating Authorities with the option to participate in a Trial. Written authorisation must be obtained from the Authority prior to the commencement date of any Trial. The Authority shall not be liable for any costs incurred by the supplier in relation to the Trial.
   3. The supplier is expected to support any required product trials or clinical evaluations as requested by the Authority and must provide samples to enable the Authority to carry out required evaluations. To enable the Authority to manage and complete a meaningful evaluation, product training and clinical guidance must also be provided.
   4. 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 the Authority/ CPP LLP of the trial start date and duration.
   5. 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 Authority.

**Evidence of Compliance**

**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 your tender submission.

1.4 Where we have stated a Standard is to be achieved, for example, Medical Devices Directive 2007/47/EC or ISO 9001:2015 – Quality Management System, this means the Standard or an equivalent.

**2. Criteria applicable across all Lots**

2.1. Standards/Directives/Legislative requirements

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| |  |  | | --- | --- | | **LEGISLATION** | **TENDER REQUIREMENTS** | | **BS EN 455-1:2020**  Medical gloves for single use. Requirements and testing for freedom from holes. The compliance level for freedom from holes for a medical glove must be an acceptable quality level (AQL) of 1.5 % and Surgical Gloves Requirement (AQL) of 0.65% | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN 455-2:2015**  Medical gloves for single use.  Requirements and testing for physical properties. The gloves are tested to determine dimensions (length and palm width) and physical strength (force at break)  Examination Gloves Requirement: >= 6.0 Newtons or >=3.6 Newtons (for all gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene)  Surgical Gloves Requirement: >=9.0 Newtons | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN 455-3:2015**  Medical gloves for single use.  Requirements and testing for biological evaluation. The gloves are tested to determine the presence of potentially hazardous material that could affect the wearer.  The manufacturer shall disclose, upon request, a list of chemical ingredients either added or already known to be present that will cause adverse health effects.  Powder-free gloves only: Removable Surface Powder: <=2mg/glove. (N.B. If the powder level is above this level, it is considered to be a powdered glove).  Labelling: shall include a prominent indication of whether the glove is powdered or powder-free.  Surgical/Sterile Gloves only: Endotoxin: <20EU (Endotoxin units)/pair of gloves.  Natural Rubber Latex Gloves only: Examination and Surgical Gloves, Total extractable protein - Result indicated in µg per gram. | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN 455-4:2009**  Medical gloves for single use.  Requirements and testing for service life determination. The gloves are tested to determine the shelf life that can be applied. Requirements and testing for shelf life determination (Only required if claiming 5 years expiry date, otherwise, for 3 years, manufacturing and expiry date on packaging is sufficient). | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN 556-1:2001**  **IF NO BS EN 556-1:2000 ASTM D3577-19 OR equivalent technical solutions IS REQUIRED**  specifies the requirements for a terminally sterilized medical device to be designated “STERILE” | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN 374-1:2016:2018**  **IF NO BS EN374-1:2016 or BS EN 374-2:2014 ASTM D6978-05 OR equivalent technical solutions IS REQUIRED**  Protective Gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks. According to their permeation performance (3 samples), chemical protective gloves are classified into three types: type A, type B, type C. Type A - The permeation performance shall be at least level 2 against a minimum of 6 test chemicals (from table of 18 chemicals).  Type B - The permeation performance shall be at least level 2 against a minimum of 3 test chemicals (from table of 18 chemicals).  Type C – The permeation performance shall be at least level 2 against a minimum of 1 test chemical (from table of 18 chemicals).  Marking – protective gloves against dangerous chemicals shall be marked in accordance with the requirements for protective glove:- | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN 374-2:2019**  **IF NO BS EN374-1:2016 or BS EN 374-2:2014 ASTM D6978-05 OR equivalent technical solutions IS REQUIRED**  Protective Gloves against dangerous chemicals and micro-organisms - Determination of resistance to penetration.  Water leak test – Pass/Fail.  Air leak test – Pass/Fail and air pressure used. | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN 16523-1:2015 (replaces BS EN 374-3:2003)**  Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN ISO 374-4:2019**  Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals.  Degradation shall be determined according to EN374-4:2019 for each chemical. The degradation result, in percentage %, shall be reported in the user instruction | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN ISO 374-5:2016**  Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks. | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN 556 -1:2001**  This European Standard specifies the requirements for a terminally sterilised medical device to be labelled "STERILE". | Test report / certification from **an ISO/IEC 17025:2005** accredited laboratory | | **BS ISO 16604:2004**  **or ASTM F1671 / F1671M – 13.**  If protection against viruses as stated in test report for EN ISO 374-5:2016, then compliance against this standard is also required. (Clothing for protection against contact with blood and body fluids)- Determination of resistance of protective clothing materials to penetration by blood-borne pathogens. | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN ISO 13485:2016 OR BS EN ISO 9001:2000 (Both or Either)**  An additional Quality Management Standard for suppliers of medical devices | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **BS EN ISO 21420:2020 (replaces EN 420:2003+A1:2009 )**  **General Requirements and test methods for Gloves.** | Test report / certification from an **ISO/IEC 17025:2005** accredited laboratory | | **Medical Devices Regulation 2017/745**  EU Regulations for medical devices (MDR) and in vitro diagnostic medical devices (IVDR) came into force on 25 May 2017 and announced transition periods of 3 years (MDR 26 May 2020) and 5 years (IVDR 26 May 2022) for full compliance in Member States.  All products must have their **CE/UKCA** marking clearly evident on the product and/or packaging. | Class I Sterile, Class I measuring, Class  IIa, Class IIb and Class III  **CE/UKCA** certificate from a notified body to be provided with your tender submission.  Declaration that all packs all are **CE/UKCA** marked in accordance with the MDR before being made available for sale | | **Personal Protective Equipment**  **Directive 2016/425**  All products must have their CE/UKCA marking clearly evident on the product and/or packaging and must conform to the relevant directive |  | | **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 |  | | **Control of Substances Hazardous to Health Regulations 2002** (as amended) | **COSHH safety data sheets** for all applicable products must be provided to NHS Supply Chain with your tender submission. | |