NHS Supply Chain

SCHEDULE A2 (A) PRODUCT SPECIFICATION

Tender for the Supply of Medical Examination Gloves

1. Introduction

The Collaborative Procurement Partnership (CPP LLP) on behalf of Supply Chain Coordination Ltd is seeking to establish a multi supplier framework agreement for Examination 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)

1.1 The Framework is for the following Lots:

Lot Number	Lot Title
1	6N Nitrile Exam Gloves
2	Specialist Examination Gloves
3	Vinyl Gloves
4	Latex Gloves

1.2 The purpose of The **Examination Gloves** 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.

1.3 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.

1.4 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.

1.5 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.

1.6 Evidence of compliance to the standards/legislation/directives must be available at tender submission and 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.

1.7 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.

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

1.9 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.

1.10 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.

1.11 All products classified as PPE or Dual Purpose must have UKCA/CE marking followed by the UK approved body/notified body number.

1.12 **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.

1.13 The NHS e-Procurement Strategy published by the Department of Health in April 2014 requires the NHS to adopt global standards including the implementation of GS1 product coding. Awarded suppliers will be expected to work with NHS Supply Chain and NHS customers during the term of the Framework Agreement to meet these requirements.

2. Criteria applicable across all product lines

2.1 Standards and Legislation

STANDARD / CERTIFICATION
Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002). Directive for active implantable medical devices, medical devices, and in vitro diagnostic medical devices (IVDs) in the UK; Or **UK PPE 2016** **UKCA (UK Conformity Assessment)** Certification mark that indicates conformity with the applicable requirements for products sold within Great Britain; and/or an existing valid **CE certificate** provided that this is still in date. **Any product that contains phthalates must be indicated on the packaging in accordance with MDR 2002 guidance.**

Equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety Every supplier MUST have this in place by the time the framework goes live

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

2.2 Medical devices are classified depending on their use and are risk based, as follows:

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

2.3 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 the Authority.

2.4 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 15223-1:2021 symbol for latex, or equivalent

2.5 All products must have a shelf life of at least 5 years from date of manufacture and 2 years on delivery into NHS Supply Chain.

2.6 Labelling – Must specify the size of the glove and must have a manufacturing and/or expiry date on the packaging.

2.7 The sterilisation process for the supply of sterile product lines must be certified by a UK Approved Body (EU notified body).

2.8 Where applicable all products must be supplied with instructions for use and disposal/recycling instructions, or symbols printed in English.

2.9 All products must be powder free.

2.10 The inner glove box should fit neatly into a standard size glove dispensing unit, where applicable.

2.11 Latex Related Conditions

2.11.1 If applicable the Supplier Must 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.

2.12 Storage

2.12.1 The Supplier shall identify any special instructions for storage.

2.13 Product Technical Information

2.13.1 The Supplier shall provide the Authority/CPP LLP with technical product information.

3. Lot Specific Requirements

Lot 1: Examination Gloves

3.1 The scope of Lot 1 is for Medical Examination gloves intended for use in a wide range of medical applications

3.2 This Lot is for non-sterile 6N nitrile examination gloves

3.2.1 The additional product legislation and directive requirements are set out as follows:

LEGISLATION	TENDER REQUIREMENTS
BS EN 455-1:2020, or equivalent 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 %	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-2:2015, or equivalent 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)	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory

LEGISLATION	TENDER REQUIREMENTS
BS EN 455-3:2015, or equivalent 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. Sterile Gloves only: Endotoxin: <20EU (Endotoxin units)/pair of gloves. Natural Rubber Latex Gloves only: Examination Gloves, Total extractable protein - Result indicated in µg per gram.	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-4:2009, or equivalent 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 17025:2017** accredited laboratory

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

3.3 Gloves must be a minimum of:

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

3.1 All product lines in this Lot are intended to be disposed of after use and must be clearly marked as such on the primary packaging to inform the user; they are not intended for sterilisation.

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

3.4 All products must be powder free e.g., Removable Surface Powder: <=2mg/glove

3.5 The inner glove box should fit neatly into a standard size glove dispensing unit, where applicable.

Lot 2: Specialist Examination Gloves

3.6 This lot covers the following scope of products:

- 3.6.1 Chemotherapy Gloves
- 3.6.2 Long Cuff Gloves
- 3.6.3 Gauntlet Gloves
- 3.6.4 9N
- 3.6.5 Sterile Gloves
- 3.6.6 Accelerator Free Gloves

3.7 **Chemotherapy Gloves**

- 3.7.1 This is for the supply of Chemotherapy safe examination gloves made from nitrile.
- 3.7.2 The additional product legislation and directive requirements are set out as follows:

LEGISLATION	**TENDER REQUIREMENTS**
BS EN 455-1:2020, or equivalent 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 %	Test report / certification from an **ISO/IEC 17025:2017**

LEGISLATION	TENDER REQUIREMENTS
	accredited laboratory
BS EN 455-2:2015, or equivalent 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)	Test report / certification from an **ISO/IEC 17025:2107** accredited laboratory
BS EN 455-3:2015, or equivalent 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. Natural Rubber Latex Gloves only: Examination Gloves, Total extractable protein - Result indicated in µg per gram.	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-4:2009, or equivalent 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 17025:2017** accredited laboratory

LEGISLATION	TENDER REQUIREMENTS
BS EN 374-1:2016:2018, or equivalent **IF NO BS EN374-1:2016 or BS EN 374-2:2014 ASTM D6978-05(2019) OR equivalent technical solutions IS REQUIRED, or equivalent** 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 17025:2017** accredited laboratory
BS EN 374-2:2019, or equivalent **IF NO BS EN374-1:2016 or BS EN 374-2:2014 ASTM D6978-05(2019) OR equivalent technical solutions IS REQUIRED, or equivalent** 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 17025:2107** accredited laboratory
BS EN 16523-1:2015+A1:2018 (replaces BS EN 374-3:2003) , or equivalent	Test report / certification from an **ISO/IEC 17025:2017**

LEGISLATION	TENDER REQUIREMENTS
Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact.	accredited laboratory
BS EN ISO 374-4:2019, or equivalent 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 17025:2017** accredited laboratory
BS EN ISO 374-5:2016, or equivalent Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.  	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
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.

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

3.8 **Long-cuff examination glove**

3.8.1 This is for the supply of Long-cuff examination gloves made from nitrile.

3.8.2 The additional product legislation and directive requirements are set out as follows:

LEGISLATION	TENDER REQUIREMENTS
BS EN 455-1:2020, or equivalent 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 %	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-2:2015, or equivalent 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)	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-3:2015, or equivalent 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).	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory

LEGISLATION	TENDER REQUIREMENTS
Labelling: shall include a prominent indication of whether the glove is powdered or powder-free. Sterile Gloves only: Endotoxin: <20EU (Endotoxin units)/pair of gloves. Natural Rubber Latex Gloves only: Examination Gloves, Total extractable protein - Result indicated in µg per gram.	
BS EN 455-4:2009, or equivalent 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 17025:2017** accredited laboratory

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

3.8.4 These gloves must be a minimum of 300mm9 All products must be powder free.

3.9 **Gauntlet Examination gloves**

3.9.1 This is for the supply of examination gloves made from nitrile.

3.9.2 These gloves must be a minimum of 400mm

3.9.3 The additional product legislation and directive requirements are set out as follows:

LEGISLATION	TENDER REQUIREMENTS
BS EN 455-1:2020, or equivalent 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 %	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-2:2015, or equivalent 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)	Test report / certification from an **ISO/IEC 17025:2107** accredited laboratory
BS EN 455-3:2015, or equivalent 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).	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory

LEGISLATION	TENDER REQUIREMENTS
Labelling: shall include a prominent indication of whether the glove is powdered or powder-free. Sterile Gloves only: Endotoxin: <20EU (Endotoxin units)/pair of gloves. Natural Rubber Latex Gloves only: Examination Gloves, Total extractable protein - Result indicated in µg per gram.	
BS EN 455-4:2009, or equivalent 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 17025:2017** accredited laboratory

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

3.10 **9N Gloves**

3.10.1 This is for the supply of 9N examination gloves made from nitrile.

3.10.2 The additional product legislation and directive requirements are set out as follows:

LEGISLATION	TENDER REQUIREMENTS
BS EN 455-1:2020, or equivalent 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 %	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-2:2015, or equivalent Medical gloves for single use.	Test report / certification from an **ISO/IEC 17025:2107**

LEGISLATION	TENDER REQUIREMENTS
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)	accredited laboratory
BS EN 455-3:2015, or equivalent 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. Sterile Gloves only: Endotoxin: <20EU (Endotoxin units)/pair of gloves. Natural Rubber Latex Gloves only: Examination Gloves, Total extractable protein - Result indicated in µg per gram.	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-4:2009, or equivalent 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 17025:2017** accredited laboratory

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

3.11 **Sterile Nitrile examination gloves**

3.11.1 This is for the supply of Sterile Nitrile examination gloves made from nitrile.

3.11.2 The additional product legislation and directive requirements are set out as follows:

LEGISLATION	TENDER REQUIREMENTS
BS EN 455-1:2020, or equivalent 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 %	Test report / certification from an **ISO/IEC 17025:2107** accredited laboratory
BS EN 455-2:2015, or equivalent 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)	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-3:2015, or equivalent 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).	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory

LEGISLATION	TENDER REQUIREMENTS
Labelling: shall include a prominent indication of whether the glove is powdered or powder-free. Sterile Gloves only: Endotoxin: <20EU (Endotoxin units)/pair of gloves. Natural Rubber Latex Gloves only: Examination Gloves, Total extractable protein - Result indicated in µg per gram.	
BS EN 455-4:2009, or equivalent 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 17025:2107**accredited laboratory
BS EN 556-1:2001, or equivalent **IF NO BS EN 556-1:2000 OR equivalent technical solutions IS REQUIRED, or equivalent** specifies the requirements for a terminally sterilized medical device to be designated "**STERILE"**	Test report / certification from an ISO/IEC 17025:2107 accredited laboratory

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

3.2 **Accelerator Free examination glove**

3.2.1 This is for the supply of Accelerator free examination gloves made from nitrile.

3.2.2 The additional product legislation and directive requirements are set out as follows:

LEGISLATION	TENDER REQUIREMENTS
BS EN 455-1:2020, or equivalent 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 %	Test report / certification from an **ISO/IEC 17025:2017**

LEGISLATION	TENDER REQUIREMENTS
	accredited laboratory
BS EN 455-2:2015, or equivalent 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)	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-3:2015, or equivalent 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. Sterile Gloves only: Endotoxin: <20EU (Endotoxin units)/pair of gloves. Natural Rubber Latex Gloves only: Examination Gloves, Total extractable protein - Result indicated in µg per gram.	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-4:2009, or equivalent 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	Test report / certification from an **ISO/IEC 17025:2107**accredited laboratory

LEGISLATION	TENDER REQUIREMENTS
date, otherwise, for 3 years, manufacturing and expiry date on packaging is sufficient).	

Lot 3: Vinyl Gloves

3.2.3 This is for the supply of examination gloves made from Thermoplastics (e.g., Vinyl).

3.2.4 The gloves must meet the following requirement:

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

3.1.1 The additional product legislation and directive requirements are set out as follows:

LEGISLATION	TENDER REQUIREMENTS
BS EN 455-1:2020, or equivalent 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 % Gloves Requirement (AQL) of 0.65%	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-2:2015, or equivalent 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)	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory

LEGISLATION	TENDER REQUIREMENTS
Examination Gloves Requirement: >= 6.0 Newtons or >=3.6 Newtons (for all gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene)	
BS EN 455-3:2015, or equivalent 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. Sterile Gloves only: Endotoxin: <20EU (Endotoxin units)/pair of gloves. Natural Rubber Latex Gloves only: Examination Gloves, Total extractable protein - Result indicated in µg per gram.	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-4:2009, or equivalent 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 17025:2017** accredited laboratory

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

Lot 4: <u>Latex Examination Gloves</u>

3.3 This is for the supply of sterile and non-sterile latex examination gloves

LEGISLATION	TENDER REQUIREMENTS
BS EN 455-1:2020, or equivalent 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 % Gloves Requirement (AQL) of 0.65%	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-2:2015, or equivalent 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)	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory
BS EN 455-3:2015, or equivalent 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. Sterile Gloves only: Endotoxin: <20EU (Endotoxin units)/pair of gloves. Natural Rubber Latex Gloves only: Examination Gloves, Total extractable protein - Result indicated in µg per gram.	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory

LEGISLATION	TENDER REQUIREMENTS
BS EN 455-4:2009, or equivalent 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 17025:2017** accredited laboratory
BS EN 556-1:2001, or equivalent **IF NO BS EN 556-1:2000 ASTM D3577-19 OR equivalent technical solutions IS REQUIRED, or equivalent** specifies the requirements for a terminally sterilized medical device to be designated “STERILE”	Test report / certification from an **ISO/IEC 17025:2017** accredited laboratory

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