Specification for Examination Gloves

1. Product Description

Name	Description / Scope
Examination Gloves	Nitrile, Latex, Vinyl and Specialist Gloves or any other suitable material. Innovative Packaging/Coatings

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

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.

2. Standards/Directives/Legislative requirements

Standard/certification
BS EN 455-1:2000 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. **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)
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: **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. The maximum being 5 years for a medical glove.
Medical Devices Directive 93/42/EEC - where applicable All products must have their CE marking clearly evident on the product and/or packaging.
Personal Protective Equipment Directive 89/686/EEC - where applicable All products must have their CE marking clearly evident on the product and/or packaging.
Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC)
Cosmetics Directive 1223/2009/EC
Control of Substances Hazardous to Health Regulations 2002 (as amended)

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 should be latex free where possible. Any products or packaging containing latex must be clearly labelled as such to inform the user.

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

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

3. EXAMINATION GLOVES

3.1. The specification is for the supply of non-sterile and sterile gloves examination gloves made from nitrile, vinyl, latex, or any other suitable material.

3.2. Must be a minimum of:

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

- Where non-latex product is provided, product and packaging must be latex free and clearly stated.
- All products must be powder free.
- All products must have a shelf life of at least 3 years from date of manufacture and 2 years on delivery.
- The inner glove box should fit neatly into a standard size glove dispensing unit.

4. NHS Supply Chain's Ethical Procurement

4.1. 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

4.2. The 'Labour Standards Assurance System' or LSAS was developed in collaboration between NHS Supply Chain and the Department of Health and Social Care to enhance the identification of issues, remediation and continuous improvement in labour standards management. The LSAS places the responsibility on the suppliers to demonstrate they have effective systems in place. It builds on principles of due diligence, extending this to routine consideration of labour standards, particularly important for suppliers doing business in countries where evidence of issues exist

4.3. The Supplier shall evidence compliance to level 1 within 6 months of contract award, level 2 within 18 months of contract award and annual audit thereafter. Appendix 14 details the audit requirements applicable to this framework once the LSAS compliance has been achieved. This will form part of the management process of the Framework Agreement.

4.4. 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.