

Specification for Gowns Surgical Face mask, Respirator masks and Eye Protection (PPE)

1. Introduction

1.1. PPE is divided into the following Lots:

Lot Number	Lot Title
1	Surgical Face masks - Type IIR
2	Respirator Masks – FFP2 & FFP3, Helmets and hoods
3	Eye Protection
4	Gowns – Sterile, non-sterile, thumb-looped

- 1.2. 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.
- 1.3. 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.
- 1.4. Evidence of compliance to the standards/legislation/directives must be available to NHS Supply Chain on request during the lifetime of this Agreement; in the event that sufficient evidence is not supplied NHS Supply Chain reserve the right to suspend product until such evidence is available.

2. Standards/Directives/Legislative requirements

STANDARD / CERTIFICATION
All products must have their CE marking clearly evident on the product and/or packaging and must conform to the relevant directive: Medical Devices 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 89/686/EEC

- 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. Lot 1 - Surgical Face masks Type IIR

- 3.1. This lot is for surgical face masks Type IIR
 - Surgical Type IIR face mask with loops/ties, no visor, no anti-fog strip
 - Surgical Type IIR face mask with loops/ties with no visor and anti-fogging strip
 - Surgical Type IIR face mask with loops/ties, with visor, with anti fogging strip
- 3.2. Standards/Directives/Legislative requirements

STANDARD / CERTIFICATION
Surgical facemasks must conform to: BS EN 14683:2019 or any equivalent standard Medical face masks. Requirements and test methods

- 3.3. Surgical facemasks are medical devices covering the mouth, nose and chin, and should be worn during any activities where there is a risk of blood, body fluids, secretions or excretions splashing onto the wearer's mouth or eyes.
- 3.4. All Type IIR facemasks must comply with the following:
 - The mask must be marked as Type IIR;
 - Must have a splash resistance pressure equal to or greater than 120mm Hg;

- Must provide a bacterial filtration efficiency (BFE) of 98% or above;
- Must be single use;
- Each mask must dispense from packaging individually;
- Must be free from chemical smells, resulting from the manufacturing process, which prevent the end user from breathing comfortably;
- Must have no residue left from the manufacturing process on the finished product which may lead to irritations on the skin;
- Must be close fitting in order to prevent venting (exhaled air 'escaping' at the sides of the mask);
- The nose band must deform when pressed to mould over the nose and cheeks and must maintain its shape over time; and
- The nose band must not kink or break when adjusted.

Masks with ties must:

- Have integral ties long enough to go around an adult head whilst wearing a surgical cap;
- The upper tie must sit at the crown of the head;
- The lower tie must be positioned to allow it to be positioned behind the neck to hold the sides of the mask against the face of the user to prevent any gaping; and
- Straps and ties must not detach from the face mask when in use.

Masks with ear loops must:

- Have elastic ear loops; and
- Ears loops must not detach from the face mask when in use.

Masks with visors must:

- Not cause visual distortion for the wearer; and
- Have an anti-fog strip and be resistant to fogging.

Masks with ties/ear loops and anti-fog strip must:

- Be resistant to fogging when worn by wearers of spectacles.

4. Lot 2 – Respirator Masks and Respirator helmets/hoods

4.1. This Lot is Respirator masks and respirator helmets/hoods

Respirator Masks:

- FFP2 unvalved
- FFP2 valved
- FFP3 unvalved
- FFP3 valved
- Fit testing kits and accessories
- Respirator helmets/hoods
- Associated respirator accessories

4.2. Standards/Directives/Legislative requirements

STANDARD / CERTIFICATION
<p>Respirator masks must conform to: BS EN 14683:2019 or any equivalent standard Medical face masks. Requirements and test methods</p> <p>BS EN 149:2001+A1:2009 or any equivalent standard Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking</p> <p>Loose fitting RPE helmets/hoods must conform to: BS EN 12941:1998+A2:2008. Respiratory protective devices. Helmet/hood to protect against particles. Requirements, testing, marking</p>

Respirator masks are medical devices to cover the nose, mouth and chin and are required both with and without inhalation/exhalation valves. The mask consists entirely or substantially of filter material. It must be designed to provide adequate sealing on the face of the wearer against the ambient atmosphere, when the skin is dry or moist and when the head is moved. Respirator masks must be classified according to their filtering efficiency and their maximum total inward leakage.

4.3. All respirator masks must comply with the following:

- Must be single use.
- Must be of moulded, duckbill, flat folded or cone style.
- Must have integral straps/ties long enough to go around an adult head whilst wearing a surgical cap.
- Straps/ties must be adjustable for fit by the user.
- The upper strap/tie should sit at the crown of the head.
- The lower strap/tie should be positioned to allow it to be positioned behind the neck to hold the sides of the mask against the face of the user to prevent any gaping.
- The nose band must deform when pressed to mould over the nose and cheeks and must maintain its shape over time.
- The nose band must not kink or break when adjusted.

4.3.1. In addition to the requirements of 4.3. Unvalved FFP2 masks must:

- The mask must be marked as FFP2.
- Not be valved.

4.3.2. In addition to the requirements of 4.3. Valved FFP2 masks must:

- The mask must be marked as FFP2.
- Be valved.

4.3.3. In addition to the requirements of 4.3. Unvalved FFP3 masks must:

- The mask must be marked as FFP3.
- Not be valved.

4.3.4. In addition to the requirements of 4.3. Valved FFP3 masks must:

- The mask must be marked as FFP3.
- Be valved.

4.3.5. Qualitative fit testing equipment for Respirator masks.

4.4. Loose fitting RPE helmets/hoods are used as an alternative if fit testing with masks is unsuccessful, the wearer has facial hair or the wearer has a health issue which is deemed unsuitable to wear a FFP3 mask. The helmets/hoods work with a powered air filtering unit which provides clean filtered air to the wearer.

All RPE helmets/hoods must comply with the following:

- Must be optically clear.
- Must be resistant to fogging.
- Must be latex free.

4.5. Associated accessories within this lot covers all spare and replacement parts for RPE helmets/hoods.

5. Lot 3 –Eye protection

5.1. A face shield or visor is a device worn on the head for covering the whole of the face and providing a barrier to liquid splashes. All face shields/visors must comply with the following:

- Must be optically clear.
- Must be resistant to fogging.
- Adjustable head band.

5.2. Eye Shields/safety glasses are devices for protecting the eyes against exposure to liquid droplets. All safety glasses must comply with the following:

- Must be optically clear.
- Must be resistant to fogging.

5.3. Standards/Directives/Legislative requirements

STANDARD / CERTIFICATION

**Visors and Eye Shields/safety glasses must conform to:
BS EN 166:2002 or any equivalent standard**
Personal eye protection. Specifications

6. Lot 6 – Gowns

6.1. This lot is for gowns and includes:

- Sterile gowns
- Non-sterile gowns – sometimes referred to as Isolation gowns
- Thumb-looped aprons

6.2. Standards/Directives/Legislative requirements

STANDARD / CERTIFICATION
<p>BS EN 13795:2019 or equivalent standard Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment. General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels. BS EN1810:2015. Must be fire resistant/ tested for laser ignition and penetration</p>

6.3. Sterile single use surgical gowns used to cover the wearer whilst in an operating theatre or environment which requires a sterile covering in such a way as to prevent exposure to potentially contaminated fluids, including those which may contain pathogens as well as helping to prevent the wearer from contaminating the clean surgical site.

6.4. Products in this Lot include:

- Sterile single use Standard Lite gown.
- Sterile single use standard gown.
- Sterile Single use Standard High-Performance gown.

Type of gown	Hydrostatic pressure	Guidance for use/ comments
Standard Lite	>20cm H ₂ O	Minimal pressure as stated in standard EN13795: 2019
Standard	>50cm H ₂ O	Minimal exposure to fluids
Standard High performance	>100cm H ₂ O	Potential risk of low levels of fluids for a limited period in all areas

6.4.1. All products in this Lot must comply with the following:

- Must be supplied sterile.
- Must be single use.
- Must be latex free.
- Must be individually packaged.
- Must contain within the packaging a sterile field to open the gown onto.
- Must be folded with the inside facing outward and the collar visible, the wearer must be able to don the gown without touching the patient facing side.
- Contain 2 absorbent hand towels placed on the top of the gown upon opening with a minimum size of 30cm by 40cm.
- Be anti-static.
- Tie lengths on the inside of the gown must be between 35cm and 50cm (+/- 10%).
- Tie lengths on the outside of the gown must be between 35cm and 75cm (+/- 10%) to prevent them touching the floor when being worn.
- Must be available in sizes S, M, L, XL as a minimum.

6.5. Non-Sterile Gowns or Isolation gowns are used for procedures that do not require a sterile product. They are required where the users need a degree of comfort and protection with low risk of fluid where simple plastic aprons do not offer enough coverage or protection. Non-Sterile Gowns are mainly used in Barrier nursing in preventing the spread of infection from one person to another in hospital and for minor procedures within the hospital or community setting.

- 6.5.1. Products in this lot include:
- Fluid resistant isolation gown - low.
 - Fluid resistant gown - medium.
 - Impervious isolation gown.

Type of gown	Hydrostatic pressure	Guidance for use/ comments
Fluid resistant isolation gown	>20cm H ₂ O – 28.4cm H ₂ O	Low exposure to fluids
Fluid resistant isolation gown	>57.3cm H ₂ O	Medium exposure to fluids
Impervious Isolation gown	>91cm H ₂ O	High exposure to fluids

- 6.5.2. All products in this Lot must comply with the following:
- Must be single use.
 - Must be latex free.
 - Must be available in sizes S, M, L as a minimum.

6.6. Thumb looped aprons are used for tasks where fully impervious non-sterile protection is needed.

- 6.6.1. All products in this Lot must comply with the following:
- The thumb loop apron is a length to give the wearer protection (below knee but above the ankle).
 - The thumb looped apron sleeves are long enough to ensure the arms are fully covered.
 - The thumb looped apron has ties to secure the apron securely around the body.