Specification for Personal Protective Clothing (PPE) to include: Gowns, Surgical Face mask, Respirator masks, Eye Protection, Protective Coveralls

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
5	Protective Coveralls

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.

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 EU 2016/425**

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.

2.5. PPE categories as per **Personal Protective Equipment Directive EU 2016/425**

PPE Category	**Category Description**	**Activity**	**Above-the-neck PPE Product Examples**
Category I	Simple PPE (PPE designed to protect users against minimal risks)	Placing product on the market – manufacturers self-declaration	Sweatbands Cold Weather Hood System Sun Capes
Category II	Intermediate PPE (PPE not covered within category I or III)	Initial Product approval	Safety spectacles Industrial helmets Bump caps
Category III	Complex PPE (PPE falling under this category includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health)	On-going surveillance through testing or factory auditing	Respiratory PPE Industrial helmets claiming Molten Metal and Electrical Resistance(EU) 2016/425 PPE Regulation change: Hearing Protection

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
Respirator masks must conform to: **BS EN 149:2001+A1:2009 or any equivalent standard** Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking **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

Respirator masks are filtering respiratory protective devices to protect against particles 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; and
- The nose band must not kink or break when adjusted.

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

- Be marked as FFP2; and
- Not be valved.

4.4.1. In addition to the requirements of 4.3. Valved FFP2 masks must:
- Be marked as FFP2; and
- Be valved.

4.4.2. In addition to the requirements of 4.3. Unvalved FFP3 masks must:
- Be marked as FFP3; and
- Not be valved.

4.4.3. In addition to the requirements of 4.3. Valved FFP3 masks must:
- Be marked as FFP3; and
- Be valved

4.4.4. Qualitative fit testing equipment for Respirator masks.

4.5. 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.

4.6. All RPE helmets/hoods must comply with the following:
- Must be optically clear;
- Must be resistant to fogging; and
- Must be latex free.

4.7. 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; and
- 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; and
- 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 4 – 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
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 EN11810:2015.** Must be fire resistant/ tested for laser ignition and penetration

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_2O	Minimal pressure as stated in standard EN13795: 2019
Standard	>50cm H_2O	Minimal exposure to fluids
Standard High performance	>100cm H_2O	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; and
- 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_2O – 28.4cm H_2O	Low exposure to fluids
Fluid resistant isolation gown	>57.3cm H_2O	Medium exposure to fluids
Impervious Isolation gown	>91cm H_2O	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;
- Be anti-static;
- Must be low linting;
- Be fire resistant;
- Cuffs must be knitted and attached to the gown via overlock stitching;
- Seams to be welded;
- Tie lengths on the inside of the gown must be between 35cm and 50 cm (+/-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; and
- Must be available in sizes M, L, XL, XXL 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; and
- The thumb looped apron has ties to secure the apron securely around the body.

7. Lot 5 – Protective Coveralls

7.1. This Lot is for coveralls/Protective Suits

7.2. Standards/Directives/Legislative requirements

STANDARD / CERTIFICATION
All Coveralls/protective suits must conform to: **BS EN 14126:2003 or any equivalent standard** Protective clothing. Performance requirements and tests methods for protective clothing against infective agents. In accordance with the requirements of **BS EN 14126:2003 or any equivalent standard** protective clothing must be subjected to 5 test methods specified in the standard. **Personal Protective Equipment Directive EU 2016/425 – Category III**
All category III type 1a, 1b, 1c and 2B coveralls/protective suits must conform to: **BS EN 943-1:2019 or any equivalent standard** Protective clothing against liquid and gaseous chemicals, aerosols and solid particles. Performance requirements for ventilated and nonventilated "gas-tight" (Type 1) and "non-gas-tight" (Type 2) chemical protective suits. **BS EN 943-2:2019 or any equivalent standard** Protective clothing against liquid and gaseous chemicals, aerosols and solid particles. Performance requirements for "gas-tight" (Type 1) chemical protective suits for emergency teams (ET).
All category III type 3B and 4B coveralls/protective suits must conform to: **BS EN 14605:2005+A1:2009 or any equivalent standard** Protective clothing against liquid chemicals. Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4]).
All category III type 5B coveralls/protective suits must conform to: **BS EN ISO 13982-1:2004+A1:2010 or any equivalent standard** Protective clothing for use against solid particulates. Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing).

7.3. Coveralls/protective suits must be designed to cover the whole body except for the hands, feet and face area, providing a barrier to air borne and fluid borne contaminants and pathogens preventing infective agents from reaching the (possibly injured) skin. Standard protective clothing should be certified as Category III and subjected to 5 test methods specified in the standard.

Definition of Category III under the PPE regs EU 2016/425

PPE Category	Category Description	Activity	Above-the-neck PPE Product Examples
Category III	Complex PPE (PPE falling under this category includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health)	On-going surveillance through testing or factory auditing	Respiratory PPE Industrial helmets claiming Molten Metal and Electrical Resistance(EU) 2016/425 PPE Regulation change: Hearing Protection

The corresponding protective clothing "Type" must then suffix with the "-B" (e.g. Type3-B) and the Biohazard symbol must be displayed on the packaging.

7.3.1. All coveralls/protective suits must comply with the following:

- Must seal effectively around the ankles, wrists and face;
- Must be antistatic;
- Must be single use;
- Must be individually packaged; and
- Must be available in sizes S, M, L as a minimum.

7.3.2. User information must include:

- Number of European standard;
- The type designation e.g. type 3-B;
- The biological agents against which the protective clothing has been teste. The information shall be expressed as performance levels for the relevant types of biological challenge; and
- Other relevant performance levels, preferably as a table.

7.3.3. The information necessary for trained persons about:

- Application and limitations of use (temperature range etc);
- Relevant checks to be carried out by wearer before use;
- Fitting and adjustments, and any accessories needed to provide the claimed level of protection;
- Use;
- Storage;
- If relevant, a warning against problems likely to be encountered; and
- If relevant, illustrations, part numbers and marking of spare parts etc.

- Disposal after use.

7.3.4. In addition to the requirements of 7.2. category III type 1a, 1b, 1c and 2B suits must:
- Be gas-tight and resistant to penetration by air borne and fluid borne pathogens.

7.3.5. In addition to the requirements of 7.2. category III type 3B suits must:
- Be liquid-tight and resistant to penetration by air borne and fluid borne pathogens.

7.3.6. In addition to the requirements of 7.2. category III type 4B suits must:
- Be spray-tight and resistant to penetration by air borne and fluid borne pathogens.

7.3.7. In addition to the requirements of 7.2. category III type 5B suits must:
- Be dust tight.