**Schedule A2 (A)**

**FRAMEWORK AGREEMENT PRODUCT SPECIFICATION**

**Single Use PPE and Medical Protective Consumables**

# 1. Introduction

1.1. The Framework Agreement is for the supply of Single Use Gowns, Single Use Drapes, Single Use PPEand Single Use ProtectiveWear including; patient and equipment drapes, gowns and outerwear, caps, shoes and aprons, facemasks and eye protection.

1.2. The Framework is divided into the following Lots:

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| **Lot**  **Number** | **Lot Title** |
| 1 | Single Use Sterile Gowns |
| 2 | Single Use Non-Sterile Gowns |
| 3 | Single Use Patient and Equipment Drapes |
| 4 | Single Use Respirators and Fit Testing Solutions |
| 5 | Single Use Face Masks Type II and Type IIR |
| 6 | Single Use Eye Protection |
| 7 | Single Use Medical Protective Wear |

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.
  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. This information will be presented with other tender documents and will be checked for compliance with notified bodies and testing houses by NHS Supply Chain.
  2. Medical devices will require registration via the MHRA. Any products which are classed as medical devices will be checked on the MHRA database.
  3. All products must have a unique product identifier and this UPI must be referenced on the documentation submitted for this framework.
  4. Each product requires a complete suite of documents for submission even if these have been submitted previously to NHS Supply Chain.
  5. 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 Lots

2.1. Standards/Directives/Legislative requirements

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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: 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);  **Medical Devices Regulation 2017/745**  **EU MDD 93/42/EEC**  **UK MDR 2002**  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 PPE 89/686/EEC**  **UK PPE 2016** |

2.2. 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.

2.3. All products and packaging must be **latex free**.

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

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

# 3. Lot 1 – Sterile Surgical Gowns

3.1. This Lot is for Sterile surgical gowns. These are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, and particulate matter.

3.2. Products in this Lot include:

* Sterile single use Standard-Lite Gown
* Sterile single use Standard Gown
* Sterile Single use Standard High-Performance gown
* Sterile Single use Zonal Reinforced Gown
* Sterile Single use Zonal Impervious Gown
* Single Use, Sterile Fully Impervious Gown

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| **Type of gown** | **Hydrostatic pressure** | **Guidance for use** |
| Standard-Lite | ≥20cm | No expected exposure to fluids |
| Standard | >50cm H20 | Minimal exposure to fluids |
| Standard High performance | >100cm H20 | Potential risk of low levels of fluids for a limited period in all areas |
| Zonal reinforced | >125cm H20 (Critical areas) | Potential contact of high- risk items with the gown in zonal areas |
| Zonal Impervious | >200cm H20 (Critical areas) | Potential risk of high levels of fluids in zonal areas for prolonged lengths of time |
| Fully Impervious | >200cm H20 | Potential risk of high levels of fluids in all areas |

3.3 Standards/Directives/Legislative requirements

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| **STANDARD / CERTIFICATION** |
| **Medical Devices Regulation 2017/745**  **EU MDD 93/42/EEC**  **UK MDR 2002**  **BS EN 13795-1:2019 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 EN 10993-1:2020, 10993-5:2020 and 10993-10:2020.**  Biological evaluation of Medical devices  or ASTM F2407-06 & ANSI/AAMI PB70:2012 or equivalent  **BS EN 556-1:2001** Sterilization of medical devices. Requirements for medical devices to be designated "STERILE".  Requirements for terminally sterilized medical devices |

3.4 All products in this Lot must comply with the following:

* Must be supplied sterile with the method of sterilisation on the labelling.
* Must be double wrapped.
* Must be single use.
* Muststate the type/description of gown.
* Muststate fluid properties/performance of the gown.
* Must be latex free.
* Must have a manufacturing and/or expiry date.
* 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.
* Shouldhave bonded, taped or overlock stitching of seams and elasticated, knitted cuffs attached to gown by overlock stitching.
* The size range must cover from 105cm (+/- 10%) from collar to the lowest point of the gown in the smallest size to 160cm (+/- 10%) in the largest size. This range should be covered in increments that do not lead to excessive amounts of gowns requiredor be available in sizes: Extra small to Extra Extra Large with Long and Extra long versions available from sizes large upwards.

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| * Must be clearly CE/UKCA marked.  |  | | --- | |  | |

**4. Lot 2- Single Use Non-Sterile Gowns**

4.1. This Lot is for Non-Sterile Gowns.

4.2. Products in this Lot include:

* Non-sterile single use Isolation Gown
* Non-sterile single use Patient Examination Gown
* Thumb looped gowns/aprons

An Isolation gown is worn as part of the PPE and is a non-sterile gown designed to protect the healthcare worker from infective agents carried in blood or body fluids of patients.

A patient gown is worn to protect the modesty of a patient whilst having a medical or surgical procedure or examination. These gowns must be opaque to maintain the dignity of the patient.

A thumb looped apron/gown is a polyethylene, single use, non-sterile product which has an opened back and is worn when a fully impervious non-sterile gown/apron is required.

4.3 Standards/Directives/Legislative requirements

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| **STANDARD / CERTIFICATION** |
| **Medical Devices Regulation 2017/745**  **EU MDD 93/42/EEC**  **UK MDR 2002**  **Thumb looped gowns/aprons: PPE Directive 2016/425**  **EU PPE 89/686/EEC**  **UK PPE 2016**  **BS EN 13795-1:2019 or equivalent standard**  AAMI Level 2, 3 or 4 (only applicable pre-April 2020 for **Isolation gowns**)  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 EN 10993-1:2020, 10993-5:2020 and 10993-10:2020.**  Biological evaluation of Medical devices  or ASTM F2407-06 & ANSI/AAMI PB70:2012 or equivalent |

4.4 All products in this Lot must comply with the following:

* Must be single use.
* Muststate the type/description of gown.
* Muststate fluid properties/performance of the gown.
* Must be latex free.
* Must have a manufacturing and/or expiry date.
* Be anti-static
* An Isolation gown shouldhave Tie lengths on the inside of the gown must be between 35cm and 50cm (+/- 10%)
* An Isolation gown shouldhave Tie lengths on the outside of the gown must be between 35cm and 75cm (+/- 10%) to prevent them touching the floor when being worn.
* The thumb loop gown/apron is a length to give the wearer protection (below knee but above the ankle).
* The thumb looped gown/apron sleeves are long enough to ensure the arms are fully covered.
* The thumb looped gown/apron has ties to secure the apron securely around the body.
* An Isolation gown shouldhave bonded, taped or overlock stitching of seams and elasticated, knitted cuffs attached to gown by overlock stitching.
* The size range must cater for sizes small to extra extra large or provide a one size gown which would accommodate these sizes.
* Patient examination gowns must be opaque to maintain the dignity of the patient.

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| * Must be clearly CE/UKCA marked.  |  | | --- | |  | |

# 5. Lot 3 – Patient and equipment drapes

5.1. Disposable patient surgical drapes are designed to provide a barrier between the unsterile skin of the patient and the sterile surgical field. They provide a bacteria-proof barrier between the unsterile surfaces they cover and the sterile surgical field which contributes to reducing the risk of surgical site infections. Drapes also help to visually mark the sterile field i.e. what can and what cannot be touched during surgery. In addition, equipment drapes cover non-sterile equipment which are used during a procedure to prevent contamination to the sterile surgical field.

* For the purpose of this tender a patient drape is defined as: a medical device which covers the patient creating a sterile field around the surgical site and which acts as a barrier to prevent the risk of surgical site infection.
* For the purpose of this tender an equipment drape is defined as: a medical device which is used to cover non-sterile equipment for use in the sterile field.

5.2. Products in this Lot include but are not limited to:

* Patient drapes/Patient drape packs;
* Equipment drapes;
* Associated products and accessories.

5.3 Standards/Directives/Legislative requirements

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| **STANDARD / CERTIFICATION** |
| **Medical Devices Regulation 2017/745**  **EU MDD 93/42/EEC**  **UK MDR 2002**  **BS EN 13795-1:2019** **or any 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 EN 556-1:2001** Sterilization of medical devices. Requirements for medical devices to be designated "STERILE".  Requirements for terminally sterilized medical devices  **BS EN 10993-1:2020, 10993-5:2020 and 10993-10:2020.**  Biological evaluation of Medical devices  or ASTM F2407-06 & ANSI/AAMI PB70:2012 or equivalent |

5.4 All drapes/drape packs must comply with the following:

* Must be antistatic.
* Must be supplied sterile (if appropriate).
* Must be single use.
* Must be latex free.
* Large drapes that require two people to apply have indicators to guide correct placement. Indicators to be words or symbols.
* Drapes have an indication on the packaging of how to open in order to maintain sterility.
* Must be individually packaged.
* Must be clearly CE/UKCA marked.

# 6. Lot 4 – Single Use Respirator Masks and Fit Testing Kits and Solutions

6.1. This Lot is for Single Use Respirator Masks associated fit testing kits and solutions.

6.2. Products in this Lot include but are not limited to:

Respirator Masks:

* + FFP2 unvalved.
  + FFP2 valved.
  + FFP3 unvalved.
  + FFP3 valved.
  + Associated fit testing kits, solutions and associated spares.

6.3 Standards/Directives/Legislative requirements

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| **STANDARD / CERTIFICATION** |
| **Respirator masks must conform to:**  **PPE Directive 2016/425**  **EU PPE 89/686/EEC**  **UK PPE 2016**  **BS EN 149:2001+A1:2009** **or any equivalent standard**  Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking |

6.4. Respirator masks are personal protective equipment that cover the nose, mouth and chin. These masks are required both with and without inhalation/exhalation valves. The mask consists entirely or substantially of filter material and 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.

6.4.1. All respirator masks must comply with the following:

* Must be single use.
* Must be single wrapped.
* Must be CE/UKCA marked with the notified body number on the mask.
* Must be marked as latex free.
* Must be of moulded, duckbill/flat folded or cone/cup style.
* Must have integral straps long enough to go around an adult head whilst wearing a surgical cap.
* The upper strap/tie should sit at the crown of the head.
* The lower strap/tie should be positioned to allow it to be sit behind the neck to hold the sides of the mask against the face of the user to prevent any gaping.

**Due to concerns about adequacy of face fit and comfort, the head harness as specified in 7.13 (BS EN 149:2001+A1:2009) must not be of a design that holds the mask in place by the ears alone (aka ear loop).**

* The mask must not use additional adjuncts on the straps to ensure a good fit of the mask.
* 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.
* The mask must be of a design that does not collapse against the mouth.

6.4.2. In addition to the requirements of 5.4.1. Unvalved FFP2 masks must:

* Be marked as FFP2.
* Not be valved.

6.4.3. In addition to the requirements of 5.4.1. Valved FFP2 masks must:

* Be marked as FFP2.
* Be valved.

6.4.4. In addition to the requirements of 5.4.1. Unvalved FFP3 masks must:

* Be marked as FFP3.
* Not be valved.

6.4.5. In addition to the requirements of 5.4.1. Valved FFP3 masks must:

* Be marked as FFP3.
* Be valved

6.5. Fit Testing Kits and solutions are intended to be used to fit test any tight-fitting particulate respirator. The kit can be used as both a test method to ensure correctly fitting masks and as an effective means of training in the correct way to fit a mask ensuring that the masks operate effectively.

This lot includes:

* Fit testing kits.
* Standalone sweet or bitter test and sensitivity solutions.
* Associated spares: nebulisers, atomisers, probes and hoods.

# 7. Lot 5 – Single Use Surgical Face Masks

7.1. This Lot is for Single Use Surgical Face Masks,

7.2. Products in this Lot include but are not limited to:

Surgical Face Masks:

* + Surgical Type II face mask with loops/ties, no visor, no antifog strip.
  + Surgical Type IIR face mask with loops/ties no visor, no antifog strip.
  + Surgical Type II face mask with loops/ties with no visor and with anti-fogging strip.
  + Surgical Type IIR face mask with loops/ties with no visor and with anti-fogging strip.
  + Surgical Type II face mask with loops/ties, with visor, with anti-fogging strip.
  + Surgical Type IIR face mask with loops/ties, with visor, with anti-fogging strip.

7.3 Standards/Directives/Legislative requirements

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| **STANDARD / CERTIFICATION** |
| **Surgical facemasks must conform to:**  **Medical Devices Regulation 2017/745.**  **EU MDD 93/42/EEC**  **UK MDR 2002**  **BS EN 14683:2019+AC:2019 or any equivalent standard**   |  | | --- | | **ASTM F2100-19** |   Medical face masks. Requirements and test methods  **BS EN 10993-1:2020, 10993-5:2020 and 10993-10:2020.**  Biological evaluation of Medical devices |

7.4. The main intended use of medical face masks is to minimise transfer of infectious agents (germs) by large- particle droplets between healthcare staff and a patient during surgical procedures and other medical/healthcare settings with similar requirements (in the case of Type II masks). Additionally, in certain circumstances it is intended to protect the wearer against splashes of potentially contaminated liquids (in the case of Type IIR masks).

7.4.1. All Type II and IIR facemasks must comply with the following:

* + - Must be single use;
    - Must be CE/UKCA marked;
    - Each mask must dispense from packaging individually;
    - Must be latex free;
    - Must be free from chemical smells, resulting from the manufacturing process, which prevent the end user from breathing comfortably;
    - 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;
    - The nose band must not kink or break when adjusted;
    - The mask must be of a design that does not collapse against the mouth;

Masks with ties must:

* Have integral ties long enough to go around an adult head;
* 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
* Ear loops must not detach from the face mask when in use.

Masks with visors must:

* Not cause visual distortion for the wearer.
* The visor must be optically clear.
* 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

In addition to the requirements in 6.4.1. Type II surgical facemasks must:

* Be marked as Type II.
* Must provide a bacterial filtration efficiency (BFE) of 98% or above.

In addition to the requirements in 6.4.1. Type IIR surgical facemasks **must:**

* Be marked as Type IIR.
* Have a splash resistance pressure equal to or greater than 120mm Hg.
* Provide a bacterial filtration efficiency (BFE) of 98% or above.

# 8. Lot 6 – Single Use Eye Protection

8.1. This Lot is for Single Use Eye Protection

8.2. Products in this Lot include but are not limited to:

* Eye Shields:
  + Single use safety glasses.
  + Single use safety goggles.
  + Single use face visors.
  + Patient intraoperative eye protection.

8.3 Standards/Directives/Legislative requirements

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| --- |
| **STANDARD / CERTIFICATION** |
| **Visors and Eye Shields/safety glasses/safety goggles must conform to:**  **PPE Directive 2016/425**  **EU PPE 89/686/EEC**  **UK PPE 2016**  **BS EN 166:2002/ EN 166:2001 or any equivalent standard**  Personal eye protection. Specifications. |

8.4. The main intended use of:

**Goggles/Glasses** – These are made with a flexible plastic frame and one or two lenses with a flexible elastic headband. Some can be worn with prescription glasses. They give the eyes protection from all angles as the complete rim is in contact with the face. They provide barrier protection to the eyes against exposure to liquid droplets and splashes.

**Face visors** – These have one large lens with a frame and adjustable head harness. Most can be worn with prescription glasses. They provide barrier protection against liquid splashes to the face but do not fully enclose the eyes.

8.5. All face shields/visors must comply with the following:

* Must be optically clear and have a degree of optical neutrality compatible with the degree of precision required.
* Should be resistant to fogging.
* Must be marked latex free.
* Have a self-adjusting Headband.
* Headband shouldbe at least 10mm wide to reduce the likelihood of pressure headaches/discomfort.
* Should cover at least the minimum area of head-form eye-region rectangle coverage and able to fully cover the sides and length of face.
* Must be resistant to splashes.
* Must be CE/UKCA marked.
* The frames must be marked with the following:
* Identification of Manufacturer
* Standard number for which this product meets
* Frame marking should include where appropriate;
* Field of use i.e. “3” (liquid – droplet or splashes”)
* Symbol for increased robustness “S”
* Frame designed to fit a small head “H”

8.6. Safety goggles/safety glasses are devices for protecting the eyes against exposure to liquid droplets. All safety goggles/safety glasses must comply with the following:

* Must be optically clear and have a degree of optical neutrality compatible with the degree of precision required.
* Must be resistant to fogging.
* Must be marked latex free.
* Goggles must provide a good seal with the skin of the face.
* Goggles must enclose the eyes and accommodate wearers with prescription glasses.
* Goggles must have an adjustable band to secure firmly around the wearers head.
* Must be resistant to droplets.
* Must be CE/UKCA marked.

8.7. Patient intra-operative eye protection are devices to protect the patient’s eyes whilst under a general anaesthetic. These devices minimise the risk of the eyes drying out under long surgery and reduce the risk of abrasions and tears to the eye:

* Must have a system to allow the device to be positioned and removed without damaging the eye or skin around the eye.
* Must be marked latex free.
* Must be clearly CE/UKCA marked.

# 9. Lot 7 – Medical Protective Wear

9.1. This Lot is for protective clothing including but not limited to:

* Theatre Headwear: Theatre caps, hoods and hijabs;
* Beard covers;
* Overshoes and over-boots;
* Scrub suits/shirts/trousers;
* Coveralls/protective suits;
* Warm up jackets.

9.2. Standards/Directives/Legislative requirements

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| **STANDARD / CERTIFICATION** |
| **All Coveralls/protective suits must conform to:**  **Medical Devices Regulation 2017/745**  **EU MDD 93/42/EEC**  **UK MDR 2002**  **PPE Directive 2016/425**  **EU PPE 89/686/EEC**  **UK PPE 2016**  **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. |
| **All category III type 3B & 4B coveralls/protective suits must conform to:**  **BS EN 14605:2005+A1:2009 or any equivalent standard**  **BS EN 14325:2018**  **BS EN 14126:2003**  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). |
| **All Category III type 6B coveralls/protective suits must conform to:**  **EN 13034:2005+A1:2009 or any equivalent standard**   |  | | --- | | **BS EN 14325:2018** |   **BS EN 14126:2003**  Protective clothing for use against liquid chemical spray and splashes. Performance requirements for light liquid spray providing protection to the full body (type 6 clothing). |
| **BS EN 13795:2019** **or any 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 EN 10993-1:2020, 10993-5:2020 and 10993-10:2020.**  Biological evaluation of Medical devices  or ASTM F2407-06 & ANSI/AAMI PB70:2012 or equivalent |

9.3. Theatre headwear is worn to cover the head and hair, providing a barrier to minimise the direct transmission of contaminants into the surgical site.

* The headwear must have a mechanism for ensuring it stays in place during normal movement and fully covers the hair.
* The theatre cap must be resistant to tearing or becoming detached from the ties.
* Must be latex free.
* Theatre caps as a minimum, must be available in the following styles:
  + Bouffant style theatre caps – with an elastic hem to secure to the head
  + Elasticated back theatre caps – with an elastic fastening at the back to secure to the head
  + Tie fastening back theatre caps – with ties at the back to secure to the head
  + Theatre Hoods– with ties that cross at the front and tie at the back to secure to the head
  + Theatre Hoods and Hijabs: Pull on – the hood or hijab must pull or be positioned over the head to cover the head and neck with a cut out for the face.
  + All theatre headwear must be CE/UKCA marked.

9.4. Beard covers are worn to cover facial hair, providing a barrier to minimise the direct transmission of contaminants into the surgical site.

* The beard cover must have a mechanism for ensuring it stays in place during normal movement.
* Must fully cover the beard.
* Beard covers must be single use.
* Must be latex free.
* Must be clearly CE/UKCA marked.

9.5. Overshoes and Over boots are designed to cover footwear, providing a barrier to minimise the direct transmission of contaminants into a designated clean area. Overshoes and over boots must comply with the following:

* Must be liquid resistant.
* Must be anti-static.
* Must be latex free.
* Overshoes must cover the whole shoe and have an integrated elasticated section to keep them secure in use.
* Over boots must have an elastic top to secure to the leg and provide coverage of the whole of the shoe and ankle.
* Can be provided as either standard covers or anti-slip.
* Must be available in multiple sizes.
* Must be clearly CE/UKCA marked.

9.6. Disposable scrub suits are intended for single use and are usually worn by nurses, surgeons, and other medical personnel during medical procedures. Disposable scrub suits are usually two pieces of apparel, a shirt and pants, and are typically made from nonwoven paper or plastic materials. Disposable scrub suits are mainly intended to provide a clean barrier in sterile environments and other clinical treatment environments.

Disposable scrub suits must comply with the following:

* Must be antistatic.
* Must be single use.
* Must be latex free.
* Must be low linting.
* Must be available in sizes between Extra Small to 4X Extra Large.
* Must be clearly CE/UKCA marked.

9.7. 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. standard protective clothing should be certified as Category III and subjected to 5 test methods specified in the standard. The corresponding protective clothing “Type” must then suffix with the “-B”

(e.g. Type4-B) and the Biohazard symbol must be displayed on the packaging.

9.7.1. 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 latex free.
* Must be individually packaged.
* Must be available in sizes between extra, extra Small and extra, extra, extra-large.
* Must be clearly CE/UKCA marked.

9.7.2. In addition to the requirements of 9.2. category III type 3B suits must:

* Be liquid proof.

9.7.3. In addition to the requirements of 9.2. category III type 4B suits must:

* Be spray tight.

9.7.4. In addition to the requirements of 9.2. category III type 5B suits must:

* + Be dust tight.

9.7.5. In addition to the requirements of 9.2. category III type 6B suits

Must give:

* Partial protection against liquid chemical splash.
* Provide protection against radioactiveparticles.

9.8. Warm up jackets are worn to keep the wearer warm whilst in an air-conditioned environment. Warm up jackets are non-sterile.

9.8.1. All warm-up jackets must:

* Have secure front fastenings.
* Must be low linting.
* Must be latex free.
* Any cuffs must be finished off to a standard where no loose threads are visible.
* Must be single use.
* Must be available in sizes Small, Medium, Large and extra-large as a minimum or a one size option which accommodates these sizes.
* Must be clearly CE/UKCA marked.

**APPENDIX 3b**

**3B FRAMEWORK AGREEMENT SPECIFICATION – TENDER REQUIREMENTS**

# 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 equivalent.

# 2. Criteria applicable across all Lots

2.1. Standards/Directives/Legislative requirements

|  |  |
| --- | --- |
| **STANDARD / DIRECTIVE / LEGISLATION** | **TENDER REQUIREMENTS** |
| All products must have their CE/UKCA marking clearly evident on the product, and/or packaging and must conform to the relevant directive: 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);  **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.    **EU MDD 93/42/EEC**  **UK MDR 2002**  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 are CE/UKCA marked in accordance with the MDR before being made available for sale.  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). |
| **Personal Protective Equipment**  **Directive 2016/425**  **EU PPE 89/686/EEC**  **UK PPE 2016** | All products must have their CE/UKCA marking clearly evident on the product and/or packaging and must conform to the  relevant directive |
| **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 **with your tender submission.** |

2.2. All products and packaging must be latex free.

# 3. Lot 1 – Single Use Sterile Gowns

3.1. Standards / Directives / Legislative requirements

|  |  |
| --- | --- |
| **STANDARD / CERTIFICATION** |  |
| **BS EN 13795-1:2019 or any 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 EN 556-1:2001** Sterilization of medical devices. Requirements for medical devices to be designated "STERILE".  Requirements for terminally sterilized medical devices  **BS EN 10993-1:2020, 10993-5:2020 and 10993-10:2020.**  Biological evaluation of Medical devices  or ASTM F2407-06 & ANSI/AAMI PB70:2012 or equivalent | * Declaration/certificate of conformity to specification must be provided with the tender submission. * EU certificate for sterility * Test report showing full compliance to EN13795:2019. * Product images. * Packaging images & label documents. * Evidence of CE/UKCA marking. * Biocompatibility test by manufacturer, including a statement evidencing the biological suitability of the product by a suitably qualified professional. * Technical data sheet. |

# 4. Lot 2 – Single Use Non-Sterile Gowns

4.1. Standards / Directives / Legislative requirements

|  |  |
| --- | --- |
| **STANDARD / CERTIFICATION** | **TENDER REQUIREMENTS** |
| **BS EN 13795-1:2019 or any equivalent standard**  AAMI Level 2, 3 or 4 (only applicable pre-April 2020 for **Isolation gowns**)    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 EN 10993-1:2020, 10993-5:2020 and 10993-10:2020.**  Biological evaluation of Medical devices  or ASTM F2407-06 & ANSI/AAMI PB70:2012 or equivalent | **Medical Devices:**   * Declaration/certificate of conformity to specification must be provided with the tender submission. * Test report showing full compliance to EN13795:2019 or equivalent. * Product images. * Packaging images & label documents. * Evidence of CE/UKCA marking. * Biocompatibility test by manufacturer including a statement evidencing the biological suitability of the product by a suitably qualified professional. * Technical data sheet.   **PPE:**   * Declaration/certificate of conformity to specification from a notified body must be provided with the tender submission. * Module B and C2 or D Certificates. * Test report showing full compliance to EN13795:2019. * Product images. * Packaging images & label documents. * Evidence of CE/UKCA marking from notified body. * Technical data sheet. |

# 5. Lot 3 – Single Use Patient and Equipment Drapes

5.1. Standards / Directives / Legislative requirements

|  |  |
| --- | --- |
| **STANDARD / CERTIFICATION** | **TENDER REQUIREMENTS** |
| **BS EN 13795-1:2019 or any 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 EN 556-1:2001** Sterilization of medical devices. Requirements for medical devices to be designated "STERILE".  Requirements for terminally sterilized medical devices  **BS EN 10993-1:2020, 10993-5:2020 and 10993-10:2020.**  Biological evaluation of Medical devices  or ASTM F2407-06 & ANSI/AAMI PB70:2012 or equivalent. | * Declaration/certificate of conformity to specification must be provided with the tender submission. * EU certificate for sterility * Test report showing full compliance to EN13795:2019. * Product images. * Packaging images & label documents. * Evidence of CE/UKCA marking. * Biocompatibility test by manufacturer including a statement evidencing the biological suitability of the product by a suitably qualified professional. * Technical data sheet. |

# 6. Lot 4 – Single Use Respirator Face Masks

6.1. Standards / Directives / Legislative requirements

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| --- | --- |
| **STANDARD / CERTIFICATION** | **TENDER REQUIREMENTS** |
| **Respirator face masks must conform to:**  **BS EN 149:2001+A1:2009 or any**  **equivalent standard**  Respiratory protective devices. Requirements and test methods.  Filtering half masks to protect against particles. Requirements, testing, marking | * Declaration/certificate of conformity to specification from a notified body must be provided with the tender submission. * Module B and C2 or D Certificates. * Test report showing full compliance to EN149:2001+A1:2009. * Product images. * Packaging images & label documents. * Instruction for use. * Evidence of CE/UKCA marking from notified body. * Technical data sheet. |

# 7. Lot 5 – Single Use Surgical Face Masks

7.1. Standards / Directives / Legislative requirements

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| --- | --- |
| **STANDARD / CERTIFICATION** | **TENDER REQUIREMENTS** |
| **Surgical facemasks must conform to:**  **BS EN 14683:2019+AC:2019 or any equivalent standard**  **ASTM F2100-19**  Medical face masks. Requirements and test methods  **BS EN 10993-1:2020, 10993-5:2020 and 10993-10:2020.**  Biological evaluation of Medical devices | * Declaration/certificate of conformity to specification must be provided with the tender submission. * Test report showing full compliance to EN14683:2019+AC:2019. * Product images. * Packaging images & label documents. * Instructions for use. * Evidence of CE/UKCA marking. * Biocompatibility test by manufacturer and statement evidencing this by a suitably qualified professional. * Technical data sheet. |

# 8. Lot 6 – Single Use Eye Protection

8.1. Standards / Directives / Legislative requirements

|  |  |
| --- | --- |
| **STANDARD / CERTIFICATION** | **TENDER REQUIREMENTS** |
| **Face Shields / Visors and safety glasses/goggles must conform to:**  **BS EN 166:2002 or any equivalent standard**  **EN166:2001**  Personal eye protection.  Specifications    **Patient intra operative eye protection:** | * Declaration/certificate of conformity to specification from a notified body must be provided with the tender submission. * Module B and C2 or D Certificates. * Test report showing full compliance to EN166:2002/EN166:2001. * Product images. * Packaging images & label documents. * Instructions for use. * Evidence of CE/UKCA marking from notified body. * Technical data sheet. * Declaration/certificate of conformity must be provided with the tender submission. * Test report. * Product images. * Packaging images & label documents. * Instructions for use. * Evidence of CE/UKCA marking. * Technical data sheet. |

# 9. Lot 7 – Single Use Medical Protective Wear

9.1. Standards / Directives / Legislative requirements

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| --- | --- |
| **STANDARD / CERTIFICATION** | **TENDER REQUIREMENTS** |
| **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. | * Declaration/certificate of conformity to specification from a notified body must be provided with the tender submission. * Module B and C2 or D Certificates. * Test report showing full compliance to EN14146:2003. * Product images. * Packaging images & label documents. * Evidence of CE/UKCA marking from notified body. * Technical data sheet. |
| **All category III 3B & 4B coveralls / protective suits must conform to:**  **BS EN 14605:2005+A1:2009 or any equivalent standard & BS EN 14325:2018**  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] | * Declaration/certificate of conformity to specification from a notified body must be provided with the tender submission. * Module B and C2 or D Certificates. * Test report showing full compliance to EN14605:2005+A1:2009. * Product images. * Packaging images & label documents. * Evidence of CE/UKCA marking from notified body. * Technical data sheet. |
| **All category III 5B coveralls / protective suits must conform to:**  **BS EN ISO 13982-1:2004+A1:2010 or any equivalent standard** | * Declaration/certificate of conformity to specification from a notified body must be provided with the tender submission. * Module B and C2 or D Certificates. * Test report showing full compliance toBS EN ISO 13982-1:2004+A1:2010 or any equivalent standard. * Product images. * Packaging images & label documents. * Evidence of CE/UKCA marking from notified body. * Technical data sheet. |
| **All category III 6B coveralls / protective suits must conform to:**  - **EN13034:2005+A1:2009 or any equivalent standard & EN14325:2018** | * Declaration/certificate of conformity to specification from a notified body must be provided with the tender submission. * Module B and C2 or D Certificates. * Test report showing full compliance to EN13034:2005+A1:2009 or any equivalent standard & EN14325:2018. * Product images. * Packaging images & label documents. * Evidence of CE/UKCA marking from notified body. * Technical data sheet. |
| **All Warm up Jackets, Theatre Caps, Beard Covers, Single Use Scrub Suits -BS EN 13795-1:2019 or any 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 EN 10993-1:2020, 10993-5:2020 and 10993-10:2020.**  Biological evaluation of Medical devices  or ASTM F2407-06 & ANSI/AAMI PB70:2012 or equivalent. | * Declaration/certificate of conformity to specification must be provided with the tender submission. * Test report showing full compliance to EN13795:2019. * Product images. * Packaging images & label documents. * Evidence of CE/UKCA marking. * Biocompatibility test by manufacturer including a statement evidencing the biological suitability of the product by a suitably qualified professional. * Technical data sheet. |
| **Overshoes-** | * Declaration/certificate of conformity to specification must be provided with the tender submission. * Product images. * Packaging images & label documents. * Evidence of CE/UKCA marking. * Technical data sheet. |