



HM Government

# Essential technical requirements for new High-Volume Manufacture of Personal Protective Equipment (PPE) and Medical Devices (MD) during COVID-19

## Who is it written by?

The Health and Safety Executive (HSE) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK.

## Updates to this document:

This document updates the essential specifications published on 5<sup>th</sup> May 2020 to provide further clarification on requirements and alternative standards.

## Who is this document for?

This guidance is for you if you want to make and supply high volumes of gowns, gloves, masks, respirators, eye protection, and coveralls to the UK to protect health and care workers from COVID-19 and the item does not have a CE mark or you wish to propose an alternative use of an existing CE marked product against the relevant legislation. The intended purpose of the product and the manufacturer's claim will trigger the applicable regulations which are:

- If intended to protect the wearer : [EU Regulation 2016/425](#) on Personal Protective Equipment (PPE)
- If intended to protect the patient: Medical Devices Regulations ([MDR 2002](#)) which implements Medical Device Directive (MDD) 93/42/EEC on medical devices (MD).

- If you claim it is dual purpose (MD and PPE), the product must comply with MDR. In addition, they must meet the relevant Essential Health and Safety Requirements (EHSR) of the PPE Regulation.

This Guidance applies only to potential manufacturing for direct Government procurement or donations for frontline NHS health and care purposes.

## **What products are covered by this guidance?**

The essential technical requirements are for gowns, gloves, masks, respirators, eye protection and coveralls where no CE mark has been obtained or where an alternative use is proposed of an existing CE marked product (see Table 1 and 2).

For the purpose of this document, the term ‘personal protective equipment’ is used to describe products that are either PPE or medical devices that are used as protective solutions in managing this pandemic.

This is a fast-moving situation and this guidance will be continually updated.

## **Purpose of the document:**

This guidance sets out the essential technical and labelling requirements for these products based on what is ‘minimally acceptable’ for manufacture in the context of the COVID-19 threat whilst maintaining essential safety requirements.

The labelling requirements are intended to ensure health and care workers can clearly identify what the product is, to use it in the appropriate clinical environment as set out in the four nations guidance on infection prevention and control for COVID-19 on recommended PPE use.

Its use is only for the duration of the COVID-19 outbreak and products must not enter regular distribution channels or be made available to users other than NHS health and care workers.

It is not to be used to replace any current purchasing agreements/standards or re-certification of CE-marked products already on the market.

# What must I do to ensure I meet the relevant essential requirement of safety in the absence of CE mark before I supply/donate to the UK?

Normally, such products must meet requirements set out in the relevant legislation as listed above and hold a valid CE mark before being placed on the market or put into service. However, bearing in mind that health and safety is the utmost priority, it is vitally important to ensure that the most appropriate PPE and medical devices are made available swiftly to ensure adequate protection to those who need it most during the COVID-19 threat.

Therefore, the European Commission has issued a [recommendation](#) to speed-up the uptake of new products, without compromising on the health and safety standards and without undue delays. PPE (HSE) or medical devices (MHRA) must provide an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425 or the requirements of Directive 93/42/EEC. However, where market surveillance authorities deem it appropriate, according to the harmonised rules they may authorise these products to be made available despite conformity assessment procedures including the affixing of CE marking, not being fully finalised. The important caveats to this are that a) they are only to supply frontline healthcare, b) they are sourced by Government and c) they are not distributed more widely. This exemption from the medical devices regulation is termed '[derogation](#)' by MHRA and 'regulatory easement' under the PPE regulation. See the OPSS document "[New High-Volume Manufacturers of COVID-19 Personal Protective Equipment \(PPE\) Guidance for Businesses](#)" for further details.

Before such COVID-19 related products can be purchased by or donated to the Government/NHS to be used by NHS healthcare workers, they must meet essential requirements to ensure they are fit for the purpose intended, will work in line with stated performance and have been assessed as such.

Both the PPE Regulation and the MDR 2002 lay down essential requirements on health, safety and performance of the products they cover. However, both EU legal frameworks are technologically neutral and do not prescribe any specific mandatory technical solutions for the design of the products. Therefore, a number of technical solutions may be used by manufacturers. The tables below set out some of these.

This approach is designed to ensure an adequate level of safety, with respect to the essential requirements of the relevant legislation, before applying for authorisation to place a product on the UK market without a CE-mark, or where an alternative use of a CE marked product is proposed. Meeting these requirements does not guarantee clearance of an application by MHRA or HSE, as relevant. The information in your application will still be scrutinised robustly by MHRA or HSE before a decision is taken on whether to allow you to supply or donate to the NHS in the UK.

The approvals process put in place by MHRA or HSE, as appropriate, includes the requirement to provide supporting evidence. You should only take action if you think you are able to meet the essential technical requirements set out in Table 1 or 2, below, as relevant to your product.

For products where a manufacturer claims a double/dual-purpose – for example if an item could be used to protect both the patient and the healthcare worker - the MHRA approval letter will cover the medical device derogation only. You must therefore also meet the relevant Essential Health and Safety Requirements (EHSR) of the PPE Regulation. In this case, the Regulators (HSE and MHRA) will work in partnership to give the relevant authorisation.

# Note on vocabulary:

**Must:** Defines the essential requirement

**Should:** Highly desirable. As time is of the essence, it is possible to consider omitting this requirement if it significantly accelerates development and production.

**Standards:** Access to harmonised and other standards from [BSI](#) and [ASTM](#) are currently free of charge. The year of the standard is given as the current version and should be used. It is acknowledged that there are a number of standards that may give comparable design and levels of safety and performance. It is not possible to list them all in this document. The standards listed are well recognised/widely used by the industry in the EU (such as BS EN standards).

**Equivalent technical solution:** A solution that must ensure a comparable level of safety and performance to well recognised/widely used standards by the industry in the EU (such as BS EN standards).

**Chinese standards:** Work is in progress by the MHRA to add Chinese Standards for medical face masks to this document such as YY/T 0969 and YY-0469 if the performance requirements are comparable to BS EN 14683 or ASTM F2100. It is prudent in the meantime to ensure that the test results/reports to these standards meet the minimum design and performance requirements in Table 1.

**[IPC guidance](#):** Four nations [UK] guidance on Infection Prevention and Control (IPC) for COVID-19. It includes Table 1, 2, 3 and 4 on PPE recommendations.

## Medical Devices:

**Surgical/Medical face mask:** 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). A medical face mask with an appropriate microbial barrier may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations (in the case of Type I).

**Medical [disposable] gloves:** Intended for use in the medical field to protect patient and healthcare staff from cross-contamination.

**Surgical gowns:** Intended to minimise the transfer of infective agents between patient and healthcare staff during surgical and other invasive procedures. The use of surgical gowns with resistance to the penetration of fluids can also reduce the risk to healthcare staff from infective agents carried in blood or body fluids. In some cases, these gowns may be supplied non-sterile (labelled as such) and therefore should be used accordingly.

## **Personal Protective Equipment (PPE):**

**Respiratory Protective Equipment (RPE):** RPE is designed to protect the wearer from breathing in harmful substances. Respirators (filtering devices) use filters to remove contaminants from the air being breathed in. They can be either:

- non-powered respirators – relying on the wearer’s breathing to draw air through the filter e.g. FFP3 respirator; or
- powered respirators – using a motor to pass air through the filter to give a supply of clean air e.g. powered air purifying respirator (PAPR).

A key component of any respirator is the filter. This can be an intrinsic part of the device or come separately so they can be changed on a reusable respirator. It is vital that the filter is effective against the hazard. For COVID-19 settings this will be a high efficiency (P3) particle filter, which will be suitable for aerosols generated during aerosol generating procedures (AGPs).

**Eye/Face Protection:** Eye/face protection for COVID-19 settings is designed to protect the wearers eyes/face from splashes and droplets of biological fluids. The main types of eye and face protection are:

- **Goggles** – 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 or are mounted on a helmet. Most can be worn with prescription glasses. They provide barrier protection against liquid splashes to the face but do not fully enclose the eyes.

**Isolation Gowns:** There is no agreed definition for Isolation gowns in the UK. In the US, The Association for the Advancement of Medical Instrumentation (AAMI) define as *“item of protective apparel used to protect the clothing of health care personnel, visitors and patients from the transfer of microorganisms and body fluids in patient isolation situations.”* An Isolation gown worn as part of the PPE ensemble for COVID-19 is a non-sterile gown designed to protect the healthcare worker from infective agents carried in blood or body fluids of COVID-19 patients.

**Coveralls:** Coveralls, also known as chemical protective suits, provide full body protection against biological fluids. There are different test standards, which if met, allow the entire garment to be assigned Type 4 (spray tight) or Type 6 (light spray). A further test must be passed to demonstrate barrier properties against infectious agents, with the designation Type 4B or Type 6B.

## Technical documentation for Medical Devices and PPE:

Minimum quality system - Plan, Do, Check, Act (ideally a quality management system in place such as ISO 9001 or ISO 13485, but not mandatory). You **must** as a minimum collect and keep Technical Documentation that shows the product meets its design specification and is validated. This **must** cover:

**Description:** A general description of the product, including any variants (for example names, model numbers and sizes) and the intended purpose for the device.

**Raw material and component documentation:** Specifications such as: details of raw materials; details and drawings of components, and/or master patterns; including descriptions and explanations necessary to understand the drawings and diagrams; quality control procedures.

**Intermediate product and sub-assembly documentation:** Specifications including appropriate drawings and/or master patterns; circuits; formulation specification; including descriptions and explanations necessary to understand the drawings and diagrams; details of all relevant manufacturing methods; procedures and processes for quality control.

**Final product documentation:** Final product specification including appropriate drawings and/or master patterns; including descriptions and explanations necessary to understand the drawings and diagrams; details of all relevant manufacturing methods; procedures and processes for quality control.

**Packaging and labelling documentation:** Packaging specifications and copies of all labels, any instructions for use and warning/precautions on its use. If the product contains natural rubber latex (NRL), it must state this on the label.

**Design verification:** The results of qualifications tests and design calculations relevant to the intended use of the product. Details of any specific standards used.


**Special Provisions for Sterile Products:** Such products should be manufactured and packaged in appropriately controlled environments. Appropriate packaging should be utilised and validated to ensure sterility. An appropriate sterilisation method for the products must be used and validated. Validation and verification reports shall be available with a description of the sterilisation method used.

**Risk analysis:** Looks at whether risks associated with the use of the product are compatible with high-level protection of health and safety and are acceptable when weighed against the benefits to the patient or user.

**Medical device post market surveillance:** Put in place mechanisms for monitoring the performance when in use. In addition, provide full details of any adverse incidents that occur in relation to derogated medical devices via the MHRA Yellow Card Scheme, specifically you can use the 'healthcare professional report form' found at: <https://yellowcard.mhra.gov.uk>.

**PPE post market surveillance:** Put in place mechanisms for monitoring the performance when in use. Provide full details of any issues in relation to PPE authorised under regulatory easement via the 'report a defective product' webpage <https://www.hse.gov.uk/work-equipment-machinery/report-defective-product.htm>

# Table 1: Medical Device Essential Technical Requirements


Medical Device Essential Technical Requirements for derogation applications to the MHRA To be read in combination with all columns <b>Must</b> defines the essential requirement. <b>Should</b> is highly desirable		
Device Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) ( <b>Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
<p><b>Surgical / Medical face mask Type I</b></p> <p>(See <a href="#">IPC guidance</a> for use of masks by hospital staff)</p> <ul style="list-style-type: none"> <li>- Single use/disposable</li> <li>- Usually non-sterile</li> </ul> 	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be made of well-established materials for this product area</li> <li>• <b>Must</b> comply with all the requirements in Table 1 of BS EN 14683 of a 'Type I' mask if it claims conformity to it, including Bacterial Filtration Rate (BFE &gt;95%).                             <ul style="list-style-type: none"> <li>- OR ASTM Level 1 (BFE &gt;95%).</li> <li>- OR equivalent solution/standard giving comparable performance</li> </ul> </li> <li>• <b>Must</b> fit closely over the nose, mouth and chin of the wearer. The use of deformable nose bands or nose bridges are recommended which can enhance fit by conforming to the nose contours.</li> </ul> <p>Label: See <a href="#">MDD Annex I Section 13.1 -13.3</a> – information to be supplied by the manufacturer and use of symbols in accordance with internationally recognised symbols including:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be labelled 'Type I' if mask claims conformity to BS EN 14683 OR have description of mask and BFE (%) if to other standards/solutions</li> <li>• <b>Must</b> have a manufacturing and/or expiry date.</li> </ul>	<p>Option 1 - BS EN 14683:2019 Medical face masks. Requirements and test methods: <b>All requirements for Type I in Table 1 of that standard</b></p> <p>OR</p> <p>Option 2 - ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks: <b>All requirements for Level 1 mask</b></p> <p>OR Option 3 - equivalent Chinese Standards</p> <p>OR Option 4 - equivalent technical solution</p>



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Device Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) ( <b>Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
<p><b>Surgical / Medical face mask Type II</b>  <a href="#">[Surgical mask]</a></p> <ul style="list-style-type: none"> <li>- Single-use</li> <li>/ disposable</li> <li>- Usually non-sterile</li> </ul> 	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> comply with all the requirements in Table 1 of BS EN 14683 of a 'Type II' mask if it claims conformity to it, including Bacterial Filtration Rate (BFE &gt;98%).                             <ul style="list-style-type: none"> <li>- OR ASTM Level 2 or 3 (BFE &gt;98%).</li> <li>- OR equivalent solution/standard giving comparable performance</li> </ul> </li> <li>• <b>Must</b> fit closely over the nose, mouth and chin of the wearer. The use of deformable nose bands or nose bridges are recommended which can enhance fit by conforming to the nose contours.</li> </ul> <p>Label: See <a href="#">MDD Annex I Section 13.1 -13.3</a> – information to be supplied by the manufacturer and use of symbols in accordance with internationally recognised symbols including:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be labelled 'Type II' if mask claims compliance to BS EN 14683 OR give description of mask and BFE (%) if to other standards/solutions</li> <li>• <b>Must</b> have a manufacturing and/or expiry date</li> </ul>	<p>Option 1 - BS EN 14683:2019 Medical face masks. Requirements and test methods: <b>All requirements for Type II in Table 1 of the standard</b></p> <p>OR Option 2 - ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks: <b>All requirements for Level 2 or 3 mask</b></p> <p>OR Option 3 - equivalent Chinese Standards</p> <p>OR Option 4 - equivalent technical solution</p>

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Device Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) ( <b>Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
<p><b>Surgical / Medical face mask Type IIR</b>  <a href="#">[Fluid resistant (Type IIR) surgical mask]</a></p> <ul style="list-style-type: none"> <li>- Single use / disposable</li> <li>- Usually non-sterile</li> </ul> 	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be made of well-established materials for this product area</li> <li>• <b>Must</b> comply with all the requirements in Table 1 of BS EN 14683 of a 'Type IIR' mask if it claims conformity to it; including Bacterial Filtration Rate (BFE &gt;98%) <b>and splash resistance</b> pressure at 16.0 kPa (120mm Hg).                             <ul style="list-style-type: none"> <li>- OR ASTM Level 2 or 3 (BFE &gt; 98%) <b>and synthetic blood</b> test at 120mmHg or 160mmHg</li> <li>- OR equivalent solution/standard giving comparable performance.</li> </ul> </li> <li>• <b>Must</b> fit closely over the nose, mouth and chin of the wearer. The use of deformable nose bands or nose bridges are recommended which can enhance fit by conforming to the nose contours.</li> </ul> <p>Label: See <a href="#">MDD Annex I Section 13.1 -13.3</a> – information to be supplied by the manufacturer and use of symbols in accordance with internationally recognised symbols including:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be labelled 'Type IIR' if mask claims compliance to BS EN 14683 OR give description of mask (such as 'splash' or 'fluid resistant') and BFE (%) if to other standards/solutions</li> <li>• <b>Must</b> have a manufacturing and/or expiry date</li> </ul>	<p>Option 1 - BS EN 14683:2019 Medical face masks. Requirements and test methods. <b>All requirements for Type IIR in Table 1 of the standard including splash resistance (monograph/test 5.2.4)</b></p> <p>OR Option 2 - ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks: <b>All requirements for Level 2 or 3 including synthetic blood test</b></p> <p>OR Option 3 - equivalent Chinese Standards</p> <p>OR Option 4 - equivalent technical solution</p>

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Device Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) ( <b>Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
<p><b>Medical surgical glove</b> <a href="#">[Disposable Glove]</a></p> <ul style="list-style-type: none"> <li>- Sterile</li> <li>- Single use/disposable</li> </ul> 	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be made of well-established materials for this product area such as polyisoprene, polychloroprene, nitrile, natural rubber latex or neoprene and <b>must</b> be powder-free</li> <li>• <b>Must</b> comply with relevant standard(s) - see next column</li> <li>• <b>Must</b> be validated as sterile – with Sterility Assurance Level (SAL) of 10<sup>-6</sup></li> <li>• Should have long cuffs, reaching well above the wrist</li> </ul> <p>Label: See <a href="#">MDD Annex I Section 13.1 -13.3</a> – information to be supplied by the manufacturer and use of symbols in accordance with internationally recognised symbols including:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be labelled STERILE along with the method of sterilisation</li> <li>• <b>Must</b> be labelled with the symbol for natural rubber latex (as per ISO 15223) on at least the smallest packaging unit and caution placed in the instructions for use against its use where there is a known allergy to natural rubber latex (where relevant)</li> <li>• <b>Must</b> have a manufacturing and/or expiry date</li> <li>• <b>Must</b> specify the size</li> </ul>	<p>Option 1 (<b>all materials</b>) BS EN 455-1:2020. All requirements and testing for freedom from holes.</p> <p>AND BS EN 455-2:2015. All requirements and testing for physical properties.</p> <p>AND BS EN 455-3:2015 All relevant requirements and testing for biological evaluation (as a minimum sections 4.1 [general], 4.2 [chemicals], 4.4 [powder free] and 4.6 [labelling]. If natural rubber latex also section 4.5)</p> <p>AND BS EN 455-4:2009 <sup>1</sup> Requirements and testing for service life determination</p> <p>AND BS EN 556-1:2001 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices</p>

<sup>1</sup> Gloves made of well-established materials/formulation should have an expiry date with a conservative date of <3 years (generally industry-wide accepted and well understood). BS EN 455-4 testing/studies may be undertaken. If not, justification shall be recorded in the technical documentation.


<p>Medical Device Essential Technical Requirements for derogation applications to the MHRA</p> <p>To be read in combination with all columns</p> <p><b>Must</b> defines the essential requirement. <b>Should</b> is highly desirable</p>		
<p>Device Type (photos for illustration purpose only)</p> <p><a href="#">[as listed in 4 nations IPC guidance]</a></p>	<p>Minimum design, performance and labelling requirements.</p> <p>(Full compliance to chosen standard/technical solution <b>must</b> be met)</p> <p>(<b>Must</b> as a minimum also collect and keep Technical Documentation)</p>	<p>Examples of relevant standards/reference documents to demonstrate design and performance met</p>
		<p>OR Option 2: ASTM <sup>2</sup> D3577-19 Standard specification for <b>Rubber</b> surgical gloves. All requirements.</p> <p>OR Option 3 - equivalent technical solutions to the above (where applicable)</p>
<p><b>Medical examination glove</b></p> <p><a href="#">[Disposable Glove]</a></p> <p>- Single use/disposable</p> <p>- Sterile or</p> <p>Non-Sterile</p>	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be made of well-established materials for this product area such as nitrile, vinyl or natural rubber latex and <b>must</b> be powder-free</li> <li>• <b>Must</b> comply with relevant standard(s) - see next column</li> <li>• <b>Must</b> be validated as sterile – with Sterility Assurance Level (SAL) of 10<sup>-6</sup> (where relevant)</li> <li>• Should have long cuffs, reaching well above the wrist</li> </ul>	<p>Option 1 (<b>all materials</b>) BS EN 455-1:2020. All requirements and testing for freedom from holes.</p> <p>AND BS EN 455-2:2015 All requirements and testing for physical properties.</p> <p>AND BS EN 455-3:2015</p> <p>All relevant requirements and testing for biological evaluation (as a minimum sections 4.1 [general], 4.2 [chemicals], 4.4 [powder free] and 4.6 [labelling]. If natural rubber latex</p>

<sup>2</sup> ASTM glove methods have an acceptable quality limit (AQL) higher than BS EN 455 which means more failures are allowed in ASTM compared to BS EN 455. This shall be considered during the review for derogation by MHRA.

Medical Device Essential Technical Requirements for derogation applications to the MHRA

To be read in combination with all columns

**Must** defines the essential requirement. **Should** is highly desirable

<p>Device Type (photos for illustration purpose only)  <a href="#">[as listed in 4 nations IPC guidance]</a></p>	<p>Minimum design, performance and labelling requirements.                  (Full compliance to chosen standard/technical solution <b>must</b> be met)                  (<b>Must</b> as a minimum also collect and keep Technical Documentation)</p>	<p>Examples of relevant standards/reference documents to demonstrate design and performance met</p>
	<p>Label: See <a href="#">MDD Annex I Section 13.1 -13.3</a> – information to be supplied by the manufacturer and use of symbols in accordance with internationally recognised symbols including:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be labelled STERILE along with the method of sterilisation (where relevant)</li> <li>• <b>Must</b> be labelled with the symbol for natural rubber latex on at least the smallest packaging unit and caution placed in the instructions for use against its use where there is a known allergy to natural rubber latex (where relevant)</li> <li>• <b>Must</b> have a manufacturing and/or expiry date</li> <li>• <b>Must</b> specify the size</li> </ul>	<p>also section 4.5) AND BS EN 455-4:2009<sup>3</sup> Requirements and testing for service life determination</p> <p>AND if sterile:</p> <p>BS EN 556-1:2001 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices</p> <p>OR Option 2<sup>4</sup> (based on material):</p> <p>ASTM D6319-19 Standard Specification for <b>Nitrile</b> Examination Gloves for Medical Application</p> <p>ASTM D3578-19 Standard Specification for <b>Rubber</b> Examination Gloves</p> <p>ASTM D5250-19 Standard Specification for <b>Poly(vinyl chloride)</b> Gloves for Medical Application (not seamed gloves)</p>

<sup>3</sup> Gloves made of well-established materials/formulation should have an expiry date with a provisional date of <3 years (generally industry-wide accepted and well understood). BS EN 455-4 testing/studies may be undertaken. If not, justification shall be recorded in the technical documentation for the shelf life claim.

<sup>4</sup> ASTM glove methods have an acceptable quality limit (AQL) higher than BS EN 455 which means more failures are allowed in ASTM compared to BS EN 455. This shall be considered during the review for derogation by MHRA.

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Device Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) <b>(Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
		ASTM D6977-19 Standard Specification for <b>Polychloroprene</b> Examination Gloves for Medical Application  OR Option 3 - equivalent technical solutions to the above where applicable
<b>Surgical gown</b>  <a href="#">[Disposable fluid repellent gown]</a>  - Sterile  - Single use / disposable	Design and Performance: <ul style="list-style-type: none"> <li>• <b>Must</b> be made of well-established materials for this product area and have considered flammability properties</li> <li>• <b>Must</b> be validated as sterile – with Sterility Assurance Level (SAL) of 10<sup>-6</sup></li> <li>• <b>Must</b> have liquid penetration properties for critical areas including front and seams (Table 1 requirements in BS EN 13795) of:                             <ul style="list-style-type: none"> <li>- 20cm H<sub>2</sub>O or above = standard performance</li> </ul>                             OR                             <ul style="list-style-type: none"> <li>- 100cm H<sub>2</sub>O or above = high performance</li> </ul>                             OR equivalent solution/standard giving comparable performance such as ASTM PB70 Level 2 or above                         </li> <li>• <b>Must</b> have tensile strength in dry and wet state of at least 20 Newtons (N) (Table 1 requirements in BS EN 13795) in both longitudinal and lateral directions. Testing <b>must</b> include weak spots such as seams.                             <ul style="list-style-type: none"> <li>- OR equivalent solution/standard giving comparable performance</li> </ul> </li> <li>• <b>Should</b> reach mid-calf in length</li> </ul>	Option 1 - BS EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods: <b>Table 1 – All requirements for Standard or High performance gown</b>  AND if sterile: BS EN 556-1:2001 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices  OR Option 2 - ASTM F2407-06 (2013) Standard specification for surgical gowns intended to be used in healthcare facilities: <b>All relevant requirements</b>  AND ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes in health care facilities:

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**Must** defines the essential requirement. **Should** is highly desirable

Device Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) ( <b>Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
	<ul style="list-style-type: none"> <li>• <b>Should</b> have bonded, taped or overlock stitching of seams and elasticated, knitted cuffs attached to gown by overlock stitching</li> </ul> <p>Label: See <a href="#">MDR Annex I Section 13.1 -13.3</a> – information to be supplied by the manufacturer and use of symbols in accordance with internationally recognised symbols including:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be labelled STERILE along with the method of sterilisation</li> <li>• <b>Must</b> state the type/description of gown</li> <li>• <b>Must</b> state fluid properties/performance of the gown</li> <li>• <b>Must</b> have a manufacturing and/or expiry date</li> <li>• <b>Must</b> include warnings on its use in certain areas (flammability) if appropriate</li> </ul>	<p><b>All relevant requirements for AAMI Level 2, 3 or 4</b></p> <p>OR Option 3 - equivalent technical solutions to the above</p>

Medical Device Essential Technical Requirements for derogation applications to the MHRA

To be read in combination with all columns

**Must** defines the essential requirement. **Should** is highly desirable

Device Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) ( <b>Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
<p><b>Surgical gown</b></p> <p><a href="#">[Disposable fluid repellent gown]</a></p> <ul style="list-style-type: none"> <li>- Non-sterile</li> <li>- Single use/disposable</li> </ul> <p>OR (<a href="#">IPC listed option where PPE shortages</a>): Reusable (in line with the manufacturer's intended use and instructions) <sup>5</sup></p>	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be made of well-established materials for this product area and have considered flammability properties</li> <li>• <b>Must</b> have liquid penetration properties for critical areas including front and seams (Table 1 requirements in BS EN 13795) of: <ul style="list-style-type: none"> <li>- 20cm H<sub>2</sub>O or above = standard performance</li> </ul> </li> <li>OR</li> <li>- 100cm H<sub>2</sub>O or above = high performance</li> <li>- OR equivalent solution/standard giving comparable performance such as ASTM PB70 Level 2 or above.</li> <li>• <b>Must</b> have tensile strength in dry and wet state of at least 20 Newtons (N) (Table 1 requirements in BS EN 13795) in both longitudinal and lateral directions. Testing <b>must</b> include weak spots such as seams. <ul style="list-style-type: none"> <li>- OR equivalent solution/standard giving comparable performance.</li> </ul> </li> <li>• <b>Must</b> maintain the above performance for reusable gowns after each reprocessing cycle.</li> <li>• <b>Should</b> be mid-calf in length</li> <li>• <b>Should</b> have bonded, taped or overlock stitching of seams and elasticated, knitted cuffs attached to gown by overlock stitching.</li> </ul>	<p>Option 1 - BS EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods: <b>Table 1 – All requirements for Standard or High performance gown</b></p> <p>OR Option 2 - ASTM F2407-06 (2013) Standard specification for surgical gowns intended to be used in healthcare facilities: <b>All relevant requirements</b></p> <p>AND ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes in health care facilities: <b>All relevant requirements for AAMI Level 2, 3 or 4</b></p> <p>OR Option 3 - equivalent technical solution to the above</p>


<sup>5</sup> Reusable gowns that are intended to be reprocessed in between uses; manufacturers should refer to BS EN 13795 for guidance. They are not the same products as single use/disposable gowns.





Medical Device Essential Technical Requirements for derogation applications to the MHRA


To be read in combination with all columns

**Must** defines the essential requirement. **Should** is highly desirable

<p>Device Type (photos for illustration purpose only)  <a href="#">[as listed in 4 nations IPC guidance]</a></p>	<p>Minimum design, performance and labelling requirements.                  (Full compliance to chosen standard/technical solution <b>must</b> be met)                  (<b>Must</b> as a minimum also collect and keep Technical Documentation)</p>	<p>Examples of relevant standards/reference documents to demonstrate design and performance met</p>
	<p>Label: See <a href="#">MDR Annex I Section 13.1 -13.3</a> – information to be supplied by the manufacturer and use of symbols in accordance with internationally recognised symbols including:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> state the type/description of gown</li> <li>• <b>Must</b> state fluid properties/performance of the gown</li> <li>• <b>Must</b> provide reprocessing instructions for reusable gowns (those intended by the manufacturer to be reprocessed) and number of cycles. These should be compatible with healthcare laundry wash processes specified in <a href="#">Health Technical Memorandum 01-04</a> Decontamination of linen for health and social care (an industrial laundry cycle that achieves 71°C for 3 minutes)</li> <li>• <b>Must</b> include warnings on its use in certain areas (flammability) if appropriate</li> <li>• <b>Must</b> have a manufacturing and/or expiry date</li> </ul>	


**Table 2: Personal Protective Equipment (PPE) Essential Technical Requirements**

PPE Essential Technical Requirements applications to HSE for authorisation. To be read in combination with all columns. <b>Must</b> defines the essential requirement. <b>Should</b> is highly desirable.		
PPE Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) <b>(Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
<p><b>FFP3 / FFP2 valved / unvalved disposable respirators</b></p>  	<p>Brief Description:</p> <ul style="list-style-type: none"> <li>A particle filtering half mask covering the nose, mouth and chin and may have inhalation and/or exhalation valve(s). The half mask consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device.</li> <li>It is intended 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.</li> <li>Air enters the particle filtering half mask and passes directly to the nose and mouth area of the facepiece or, via an inhalation valve(s) if fitted. The exhaled air flows through the filter material and/or an exhalation valve (if fitted).</li> </ul> <p>Design and Performance:</p> <ul style="list-style-type: none"> <li><b>Must</b> meet <b>all</b> the requirements in BS EN 149:2001+A1:2009 <b>except</b> 7.6, 7.11, 7.14, 7.17 and 7.18.</li> <li>OR equivalent technical solutions to the above.</li> </ul> <p><b>Note:</b> Due to concerns about adequacy of face fit and comfort, the head harness as specified in 7.13 (BS EN 149:2001+A1:2009) <b>must not</b> be of a design that holds the mask in place by the ears alone (aka ear loop).</p> <p><b>Note:</b> As part of meeting the requirement set out in 7.10 Compatibility with Skin (BS EN 149:2001+A1:2009), manufacturers are reminded that Natural Rubber Latex (NRL) <b>must not</b> be used as a material.</p>	<p>BS EN 149:2001+A1:2009 Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking.</p> <p>Essential Health and Safety Requirements <a href="#">Annex II of PPE Regulation (EU) 2016/425</a> – Sections 1, 2 and 3.10.1</p>

<p>PPE Essential Technical Requirements applications to HSE for authorisation.            To be read in combination with all columns.  <b>Must</b> defines the essential requirement. <b>Should</b> is highly desirable.</p>		
<p>PPE Type (photos for illustration purpose only)  <a href="#">[as listed in 4 nations IPC guidance]</a></p>	<p>Minimum design, performance and labelling requirements.            (Full compliance to chosen standard/technical solution <b>must</b> be met)  <b>(Must</b> as a minimum also collect and keep Technical Documentation)</p>	<p>Examples of relevant standards/reference documents to demonstrate design and performance met</p>
	<p>Marking and Packaging Requirements:</p> <ul style="list-style-type: none"> <li><b>Must</b> be as specified in BS EN 149:2001+A1:2009 OR equivalent.</li> </ul> <p>Manufacturer's Instructions and Information to be provided:</p> <ul style="list-style-type: none"> <li><b>Must</b> be as specified in BS EN 149:2001+A1:2009 OR equivalent.</li> </ul>	
<p><b>Re-usable half mask respirator – with P3 particle filter</b></p> 	<p>Brief Description:</p> <ul style="list-style-type: none"> <li>A half mask which covers the nose, mouth and chin.</li> <li>It is intended 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.</li> <li>Air enters the facepiece via a particle filter (P3) and passes directly to the nose and mouth area of the facepiece. The exhaled air flows directly to the ambient atmosphere, via the exhalation valve(s) or by other appropriate means.</li> </ul> <p>Design and Performance:</p> <ul style="list-style-type: none"> <li><b>Must</b> meet <b>all</b> the requirements in BS EN 140:1999 <b>except</b> 6.2, 6.4, 6.5 and 6.6.</li> <li><b>Must</b> meet <b>all</b> the requirements in BS EN 143:2000 <b>except</b> 7.2, 7.10 and 7.13.</li> <li>OR equivalent technical solutions to the above.</li> <li><b>Must</b> be constructed of materials that can be easily cleaned and disinfected i.e. non-absorbent.</li> <li><b>Must</b> be resistant to the disinfectant products recommended by manufacturers, and these disinfectant products must have no adverse effect on the user when used in accordance with the relevant instructions.</li> </ul>	<p>BS EN 140:1999 Respiratory protective devices – Half masks and quarter masks - Requirements, testing, marking.</p> <p>BS EN 143:2000 Respiratory protective devices – Particle filters - Requirements, testing, marking.</p> <p>Essential Health and Safety Requirements <a href="#">Annex II of PPE Regulation (EU) 2016/425</a> – Sections 1, 2 and 3.10.1</p>

<p>PPE Essential Technical Requirements applications to HSE for authorisation.            To be read in combination with all columns.  <b>Must</b> defines the essential requirement. <b>Should</b> is highly desirable.</p>		
<p>PPE Type (photos for illustration purpose only)  <a href="#">[as listed in 4 nations IPC guidance]</a></p>	<p>Minimum design, performance and labelling requirements.            (Full compliance to chosen standard/technical solution <b>must</b> be met)  <b>(Must</b> as a minimum also collect and keep Technical Documentation)</p>	<p>Examples of relevant standards/reference documents to demonstrate design and performance met</p>
	<p><b>Note:</b> As part of meeting the requirement set out in 6.13 Compatibility with Skin (BS EN 140:1999) manufacturers are reminded that Natural Rubber Latex (NRL) <b>must not</b> be used as a material.</p> <p>Marking and Packaging Requirements:</p> <ul style="list-style-type: none"> <li>▪ <b>Must</b> be as specified in BS EN 140:1999 and BS EN 143:2000 OR equivalent</li> </ul> <p>Manufacturer's Instructions and Information to be provided:</p> <ul style="list-style-type: none"> <li>▪ <b>Must</b> be as specified in BS EN 140:1999 and BS EN 143:2000 OR equivalent.</li> <li>▪ <b>Must</b> be supplied with specific instructions for cleaning and disinfection. <b>Note:</b> Where more than one disinfection option is provided in manufacturer's instructions, it is up to individual Trusts and Health Boards to assess which option fits best with disinfection and re-use within their own organisation.</li> </ul> <p><b>Note:</b> P3 filters are separate consumables and must be compatible with the model of respirator. This shall be stated on the information provided with the mask/filter.</p>	
<p><b>Re-usable half mask respirator without inhalation valves – with separable P3 particle filter</b></p>	<p>Brief Description:</p> <ul style="list-style-type: none"> <li>• A half mask which covers the nose, mouth and chin, has no inhalation valves and may or may not have exhalation valves.</li> <li>• It comprises a facepiece and separable and replaceable P3 filters.</li> <li>• It is intended 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, or the wearer is speaking.</li> </ul>	<p>BS EN 1827:1999 + A1:2009            Respiratory protective devices - Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only - Requirements, testing, marking</p>

<p>PPE Essential Technical Requirements applications to HSE for authorisation.            To be read in combination with all columns.  <b>Must</b> defines the essential requirement. <b>Should</b> is highly desirable.</p>		
<p>PPE Type (photos for illustration purpose only)  <a href="#">[as listed in 4 nations IPC guidance]</a></p>	<p>Minimum design, performance and labelling requirements.            (Full compliance to chosen standard/technical solution <b>must</b> be met)  <b>(Must</b> as a minimum also collect and keep Technical Documentation)</p>	<p>Examples of relevant standards/reference documents to demonstrate design and performance met</p>
	<ul style="list-style-type: none"> <li>Inhalation air enters through the filter and passes directly to the nose and mouth area of the device. Exhaled air passes through the filter and an exhalation valve (if fitted).</li> </ul> <p>Design and Performance:</p> <ul style="list-style-type: none"> <li><b>Must</b> meet <b>all</b> the requirements in BS EN 1827:1999+A1:2009 <b>except</b> 7.2, 7.5, 7.15 and 7.17.</li> <li>OR equivalent technical solutions to the above.</li> <li><b>Must</b> be constructed of materials that can be easily cleaned and disinfected i.e. non-absorbent.</li> <li><b>Must</b> be resistant to the disinfectant products recommended by manufacturers, and these disinfectant products must have no adverse effect on the user when used in accordance with the relevant instructions.</li> </ul> <p><b>Note:</b> As part of meeting the requirement set out in 7.18 Compatibility with Skin (BS EN 1827:1999 + A1:2009), manufacturers are reminded that Natural Rubber Latex (NRL) <b>must not</b> be used as a material.</p> <p>Marking and Packaging Requirements:</p> <ul style="list-style-type: none"> <li><b>Must</b> be as specified in BS EN 1827:1999 + A1:2009 OR equivalent.</li> </ul> <p>Manufacturer's Instructions and Information to be provided:</p> <ul style="list-style-type: none"> <li><b>Must</b> be as specified in BS EN 1827:1999 + A1:2009 OR equivalent.</li> <li><b>Must</b> be supplied with specific instructions for cleaning and disinfection. <b>Note:</b> Where more than one disinfection option is provided in manufacturer's instructions, it</li> </ul>	<p>Essential Health and Safety Requirements <a href="#">Annex II of PPE Regulation (EU) 2016/425</a> – Sections 1, 2 and 3.10.1</p>


<p>PPE Essential Technical Requirements applications to HSE for authorisation.            To be read in combination with all columns.  <b>Must</b> defines the essential requirement. <b>Should</b> is highly desirable.</p>		
<p>PPE Type (photos for illustration purpose only)  <a href="#">[as listed in 4 nations IPC guidance]</a></p>	<p>Minimum design, performance and labelling requirements.            (Full compliance to chosen standard/technical solution <b>must</b> be met)  <b>(Must</b> as a minimum also collect and keep Technical Documentation)</p>	<p>Examples of relevant standards/reference documents to demonstrate design and performance met</p>
	<p>is up to individual Trusts and Health Boards to assess which option fits best with disinfection and re-use within their own organisation.</p>	
<p><b>Re-usable full mask respirator – with P3 particle filter</b></p> 	<p>Brief Description:</p> <ul style="list-style-type: none"> <li>• A full face mask covers the eyes, nose, mouth and chin and provides adequate sealing of the face of the wearer against the ambient atmosphere when the skin is dry or moist and when the head is moved, or the wearer is speaking.</li> <li>• Air enters the mask through the P3 filter(s) and passes either directly to the nose</li> <li>• An inner mask may be used to separate the nose and mouth from the eye (visor) areas of the full face mask.</li> <li>• The device must be able to be fitted with one or more replaceable P3 particle filters.</li> </ul> <p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> meet <b>all</b> the requirements in BS EN 136:1998 <b>except</b> 7.2, 7.4, 7.5, 7.6, 7.7, 7.10, 7.11.5 and 7.13.3</li> <li>• <b>Must</b> meet <b>all</b> the requirements in BS EN 143:2000 <b>except</b> 7.2, 7.10 and 7.13</li> <li>• OR equivalent technical solutions to the above.</li> <li>• <b>Must</b> be constructed of materials that can be easily cleaned and disinfected i.e. non-absorbent.</li> <li>• <b>Must</b> be resistant to the disinfectant products recommended by manufacturers, and these disinfectant products must have no adverse effect on the user when used in accordance with the relevant instructions.</li> </ul>	<p>BS EN 136:1998 Respiratory protective devices – Full face masks - Requirements, testing, marking.</p> <p>BS EN 143:2000 Respiratory protective devices – Particle filters - Requirements, testing, marking.</p> <p>Essential Health and Safety Requirements <a href="#">Annex II of PPE Regulation (EU) 2016/425</a> – Sections 1, 2 and 3.10.1</p>

<p>PPE Essential Technical Requirements applications to HSE for authorisation.            To be read in combination with all columns.  <b>Must</b> defines the essential requirement. <b>Should</b> is highly desirable.</p>		
<p>PPE Type (photos for illustration purpose only)  <a href="#">[as listed in 4 nations IPC guidance]</a></p>	<p>Minimum design, performance and labelling requirements.            (Full compliance to chosen standard/technical solution <b>must</b> be met)  <b>(Must</b> as a minimum also collect and keep Technical Documentation)</p>	<p>Examples of relevant standards/reference documents to demonstrate design and performance met</p>
	<p><b>Note:</b> As part of meeting the requirement set out in 7.17 Compatibility with Skin (BS EN 136:1998), manufacturers are reminded that Natural Rubber Latex (NRL) <b>must not</b> be used as a material.</p> <p>Marking and Packaging Requirements:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be as specified in BS EN 136:1998 and BS EN 143:2000 OR equivalent.</li> </ul> <p>Manufacturer's Instructions and Information to be provided:</p> <ul style="list-style-type: none"> <li>▪ <b>Must</b> be as specified in BS EN 136:1998 and BS EN 143:2000 OR equivalent.</li> <li>▪ <b>Must</b> be supplied with specific instructions for cleaning and disinfection. <b>Note:</b> Where more than one disinfection option is provided in manufacturer's instructions, it is up to individual Trusts and Health Boards to assess which option fits best with disinfection and re-use within their own organisation.</li> </ul> <p><b>Note:</b> P3 filter(s) are separate consumables and must be compatible with the model of respirator. This shall be stated on the information provided with the mask/filter.</p>	
<p><b>Powered Respirator with hoods/helmet – with P3 particle filters</b>            (aka Powered air purifying Respirators; PAPR)</p>	<p>Brief Description:</p> <p>The device typically consists of:</p> <ul style="list-style-type: none"> <li>• a facepiece which can be a hood as defined in EN 132 or a device which seals on the face, excluding facepieces specified in EN 136 or EN 140. Either type of facepiece may incorporate a helmet, e.g. to provide head protection against mechanical impact and/or a visor to provide eye and face protection against given risks, possibly combined;</li> </ul>	<p>BS EN 12941 1998+A2:2008            Respiratory protective devices - Powered filtering devices incorporating a loose-fitting respiratory interface - Requirements, testing, marking.</p>



PPE Essential Technical Requirements applications to HSE for authorisation.

To be read in combination with all columns.

**Must** defines the essential requirement. **Should** is highly desirable.

PPE Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) <b>(Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
	<ul style="list-style-type: none"> <li>• a turbo unit designed to be carried/worn by the wearer which supplies filtered ambient air to the facepiece. The energy supply for the turbo unit may or may not be carried on the person;</li> <li>• a filter or filters through which all air supplied passes; and</li> <li>• exhalation valves or other outlets depending on the design by which exhaled air and air in excess of the wearer's demand is discharged.</li> </ul> <p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> meet <b>all</b> the requirements in BS EN 12941:1998+A2:2008 <b>except</b> 6.2, 6.8 and 6.14.</li> <li>• OR equivalent technical solutions to the above.</li> <li>• <b>Must</b> be constructed of materials that can be easily cleaned and disinfected i.e. non-absorbent.</li> <li>• <b>Must</b> be resistant to the disinfectant products recommended by manufacturers, and these disinfectant products must have no adverse effect on the user when used in accordance with the relevant instructions.</li> </ul> <p><b>Note:</b> As part of meeting the requirement set out in 6.12 Compatibility with Skin (BS EN 12941 1998+A2:2008), manufacturers are reminded that Natural Rubber Latex (NRL) <b>must not</b> be used as a material.</p> <p>Marking and Packaging Requirements:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be as specified in BS EN 12941 1998+A2:2008 OR equivalent</li> </ul> <p>Manufacturer's Instructions and Information to be provided:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be as specified in BS EN 12941 1998+A2:2008 OR equivalent.</li> </ul>	<p>Essential Health and Safety Requirements <a href="#">Annex II of PPE Regulation (EU) 2016/425</a> – Sections 1, 2 and 3.10.1</p>




<p>PPE Essential Technical Requirements applications to HSE for authorisation.            To be read in combination with all columns.  <b>Must</b> defines the essential requirement. <b>Should</b> is highly desirable.</p>		
<p>PPE Type (photos for illustration purpose only)  <a href="#">[as listed in 4 nations IPC guidance]</a></p>	<p>Minimum design, performance and labelling requirements.            (Full compliance to chosen standard/technical solution <b>must</b> be met)  <b>(Must</b> as a minimum also collect and keep Technical Documentation)</p>	<p>Examples of relevant standards/reference documents to demonstrate design and performance met</p>
	<ul style="list-style-type: none"> <li><b>Must</b> be supplied with specific instructions for cleaning and disinfection. <b>Note:</b> It is up to individual Trusts and Health Boards to assess whether the reprocessing instructions are acceptable in their own organisation.</li> </ul>	
<p><b>Full face visor</b></p>  <p><b>Goggles</b></p> 	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>Visors and Goggles <b>must</b> meet <b>all</b> the following requirements of BS EN 166:2002 - 6.1, 6.2, 6.3, 7.1.3 and 7.2.4.</li> <li>Goggles <b>must</b> and visors <b>should</b> be resistant to fogging (7.3.2 of EN166)</li> <li>Visors only - <b>Should</b> cover at least the minimum area of head-form eye-region rectangle coverage (7.2.4b of EN166)</li> <li>Visors only - Headband <b>should</b> be at least 10mm wide to reduce the likelihood of pressure headaches/discomfort.</li> <li><b>Must</b> be optically clear and have a degree of optical neutrality compatible with the degree of precision required.</li> <li><b>Must</b> be resistant to droplets (goggles) and splashes (visors).</li> <li>Reusable equipment <b>must</b> be compatible with the reprocessing and decontamination instructions recommended by manufacturers. Any chemicals used for reprocessing and decontamination must have no adverse effect on the user when used in accordance with the relevant instructions.</li> </ul> <p><b>Note:</b> As part of meeting the requirement set out in 6.2 Materials (BS EN 166:2002), manufacturers are reminded that Natural Rubber Latex (NRL) <b>must not</b> be used as a material.</p>	<p>BS EN 166:2002 Personal eye protection</p> <p>Essential Health and Safety Requirements <a href="#">Annex II of PPE Regulation (EU) 2016/425</a> – Sections 1, 2 and 3.10.2</p>

<p>PPE Essential Technical Requirements applications to HSE for authorisation.            To be read in combination with all columns.  <b>Must</b> defines the essential requirement. <b>Should</b> is highly desirable.</p>		
<p>PPE Type (photos for illustration purpose only)  <a href="#">[as listed in 4 nations IPC guidance]</a></p>	<p>Minimum design, performance and labelling requirements.            (Full compliance to chosen standard/technical solution <b>must</b> be met)  <b>(Must</b> as a minimum also collect and keep Technical Documentation)</p>	<p>Examples of relevant standards/reference documents to demonstrate design and performance met</p>
	<p>Marking and Packaging Requirements:</p> <ul style="list-style-type: none"> <li>▪ <b>Must</b> be as specified in BS EN 166:2002 OR equivalent</li> <li>▪ Reusable equipment <b>should</b> be marked with the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded.</li> </ul> <p>Manufacturer's Instructions and Information to be provided:</p> <ul style="list-style-type: none"> <li>▪ <b>Must</b> be as appropriate and as specified in BS EN 166:2002 OR equivalent.</li> <li>▪ If designed to be re-useable, <b>must</b> be supplied with specific instructions for cleaning and disinfection. <b>Note:</b> It is up to individual Trusts and Health Boards to assess whether the reprocessing instructions are acceptable in their own organisation.</li> </ul>	
<p><b>Fluid repellent/resistant long-sleeved gown</b>            - aka Isolation Gown            - Non-sterile            - Single use / disposable</p>	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be made of well-established materials for this product area;</li> <li>• Seams <b>should</b> be either welded, stitched and taped or overlapped stitched;</li> <li>• Cuffs <b>must</b> be of a design that holds the sleeve in place e.g. elasticated, knitted and attached to the gown by overlock stitching;</li> <li>• <b>Should</b> reach mid-calf in length;</li> <li>• <b>Must</b> have liquid penetration properties for critical areas including front and sleeves (Table 1 requirements in BS EN 13795) of:              - 20cm H<sub>2</sub>O or above = standard performance              OR</li> </ul>	<p>BS EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods.</p> <p>ASTM F2407-06 (2013) Standard specification for surgical gowns intended to be used in healthcare facilities.</p> <p>ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel</p>

PPE Essential Technical Requirements applications to HSE for authorisation.

To be read in combination with all columns.


**Must** defines the essential requirement. **Should** is highly desirable.

PPE Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) <b>(Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
	<p>- 100cm H<sub>2</sub>O or above = high performance (<b>Note:</b> For a gown to be labelled as high performance the seams must also meet this requirement)</p> <p>OR equivalent solution/standard giving comparable performance such as ASTM PB70 Level 2 or above.</p> <ul style="list-style-type: none"> <li>• <b>Must</b> have tensile strength in dry and wet state of at least 20 Newtons (N) (Table 1 requirements in BS EN 13795) in both longitudinal and lateral directions. Testing <b>must</b> include weak spots such as seams.</li> <li>- OR equivalent solution/standard giving comparable performance.</li> </ul> <p>Label:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> state the type/description of gown e.g. non-sterile Isolation gown (disposable).</li> <li>• <b>Must</b> state that the gown is fluid resistant and the performance level e.g. standard or high.</li> </ul>	<p>and drapes in health care facilities.</p> <p>Essential Health and Safety Requirements <a href="#">Annex II of PPE Regulation (EU) 2016/425</a> – Sections 1 and 2</p>
<p><b>Fluid repellent/resistant long-sleeved gown</b></p> <p>- aka Isolation Gown</p> <p>- Non-sterile</p> <p>- re-usable (in line with the manufacturer's</p>	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be made of well-established materials for this product area;</li> <li>• Seams <b>should</b> be either welded, stitched and taped or overlapped stitched;</li> <li>• Cuffs <b>must</b> be of a design that holds the sleeve in place e.g. elasticated, knitted and attached to the gown by overlock stitching;</li> <li>• <b>Should</b> reach mid-calf in length;</li> <li>• <b>Must</b> have liquid penetration properties for critical areas including front and sleeves (Table 1 requirements in BS EN 13795) of: <ul style="list-style-type: none"> <li>- 20cm H<sub>2</sub>O or above = standard performance</li> </ul> </li> </ul> <p>OR</p>	<p>BS EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods.</p> <p>ASTM F2407-06 (2013) Standard specification for surgical gowns intended to be used in healthcare facilities.</p> <p>ANSI/AAMI PB70:2012 Liquid barrier performance and</p>

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<p>intended use and instructions)<sup>6</sup></p> 	<p>- 100cm H<sub>2</sub>O or above = high performance (<b>Note:</b> For a gown to be labelled as high performance the seams must also meet this requirement) OR equivalent solution/standard giving comparable performance such as ASTM PB70 Level 2 or above.</p> <ul style="list-style-type: none"> <li>• <b>Must</b> achieve tensile strength in dry/wet state of at least 20 Newtons (N) (Table 1 BS EN 13795-1:2019) in both longitudinal and lateral directions. Testing <b>must</b> include weak spots such as seams.</li> <li>• - OR equivalent solution/standard giving comparable performance.</li> <li>• <b>Must</b> maintain the performance requirements above after each reprocessing cycle (Testing <b>must</b> detail number of cycles using a specified reprocessing method). These should be compatible with healthcare laundry wash processes specified in <a href="#">Health Technical Memorandum 01-04</a> Decontamination of linen for health and social care (an industrial laundry cycle that achieves 71°C for 3 minutes).</li> </ul> <p>Label:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> state the type/description of gown e.g. non-sterile Isolation gown (re-usable)</li> <li>• <b>Must</b> state that the gown is fluid resistant and the performance level e.g. standard or high.</li> </ul> <p>Instructions:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> provide reprocessing instructions and number of cycles.</li> </ul>	<p>classification of protective apparel and drapes in health care facilities.</p> <p>Essential Health and Safety Requirements <a href="#">Annex II of PPE Regulation (EU) 2016/425</a> – Sections 1 and 2</p>

<sup>6</sup> Reusable gowns that are intended to be reprocessed in between uses; manufacturers should refer to BS EN 13795 for guidance. They are not the same products as single use/disposable gowns.

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<p><b>Type 6B Coverall</b></p> 	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> meet <b>all</b> the requirements in BS EN 13034:2005 + A1:2009.</li> <li>• <b>Must</b> meet at <b>least Class 2</b> (as specified in Table 1 of BS EN 14126:2003) for resistance to penetration by contaminated liquids under hydrostatic pressure.</li> <li>• OR equivalent solution/standards giving comparable performance to the above.</li> </ul> <p><b>Note:</b> As part of meeting the requirement set out in 4.1 Materials (BS EN 13034:2005 +A1:2009), manufacturers are reminded that Natural Rubber Latex (NRL) <b>must not</b> be used as a material.</p> <p>Marking and Information for User:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be as specified in BS EN 13034:2005 +A1:2009 and BS EN 14126:2003 OR equivalent.</li> </ul>	<p>BS EN 13034:2005 +A1:2009 Protective clothing against liquid chemicals — Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)</p> <p>BS EN 14325:2018 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages</p> <p>BS EN 14126:2003 Protective Clothing – Performance Requirements and Test methods for protective clothing against infective agents.</p> <p>Essential Health and Safety Requirements <a href="#">Annex II of PPE Regulation (EU) 2016/425</a> – Sections 1 and 2</p>

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<p><b>Type 4B Coverall</b></p> 	<p>Design and Performance:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> meet <b>all</b> the requirements for Type 4 in BS EN 14605:2005 + A1:2009.</li> <li>• <b>Must</b> meet at <b>least Class 6</b> (as specified in Table 1 of BS EN 14126:2003) for resistance to penetration by contaminated liquids under hydrostatic pressure.</li> <li>• OR equivalent solution/standards giving comparable performance to the above.</li> </ul> <p><b>Note:</b> As part of meeting the requirement set out in 4.1 Materials (BS EN 14605:2005+A1:2009), manufacturers are reminded that Natural Rubber Latex (NRL) <b>must not</b> be used as a material.</p> <p>Marking and Information for User:</p> <ul style="list-style-type: none"> <li>• <b>Must</b> be as specified in BS EN 14605:2005 + A1:2009 +A1:2009 and BS EN 14126:2003 OR equivalent.</li> </ul>	<p>BS EN 14605:2005+A1: 2009 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])</p> <p>BS EN 14325:2018 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages</p> <p>BS EN 14126:2003 Protective Clothing – Performance Requirements and Test methods for protective clothing against infective agents.</p> <p>Essential Health and Safety Requirements <a href="#">Annex II of PPE Regulation (EU) 2016/425</a> – Sections 1 and 2</p>

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<p><b>Disposable Plastic Apron</b></p> <ul style="list-style-type: none"> <li>- aka thumb loop apron or thumb loop gown</li> <li>- polyethylene</li> <li>- open backed</li> <li>- single use</li> <li>- non-sterile</li> </ul> 	<p><b>Design and Performance:</b></p> <ul style="list-style-type: none"> <li>• <b>Should</b> be made of low-density polyethylene (LDPE).</li> <li>• <b>Must</b> not contain natural rubber latex.</li> <li>• <b>Must</b> be of a length that is below the knee but above the ankle with sleeves long enough to ensure the arms are fully covered.</li> <li>• <b>Must</b> have ties that secure the apron around the body (that tie at back or side not at the front where more likely to be contaminated).</li> <li>• Over the head designs <b>should</b> be perforated to facilitate removal so that the head loop doesn't have to be pulled over the head when doffing.</li> <li>• Where made from LDPE <b>must</b> have a minimum gravimetric thickness of 21.5 microns (MU or □m)/0.0215 millimetres (mm) (BS 2782-6 Methods 631A:1994) (<b>Note:</b> this will be equivalent to a minimum weight of 20 grams per square metre gsm) OR equivalent solution/standard giving comparable performance.</li> <li>• <b>Should</b> have an impact strength of ≥30g (BS EN ISO 7765-1:2004)</li> <li>• <b>Should</b> have tear resistance ≥60mN (machine direction) (BS EN ISO 6383-2:2004)</li> </ul> <p><b>Labelling requirements:</b></p> <ul style="list-style-type: none"> <li>• The outer packaging <b>must</b> indicate the type/description of product.</li> <li>• The outer packaging <b>should</b> state the following: <ul style="list-style-type: none"> <li>- the material from which the apron is manufactured for example, low density polyethylene (LDPE)</li> <li>- single use</li> <li>- latex free</li> <li>- non-sterile</li> </ul> </li> </ul> <p><b>Note:</b> Any colour/opacity requirements as specified by end-user.</p>	<p>Essential Health and Safety Requirements Annex II of PPE Regulation (EU) 2016/425 – Sections 1 and 2</p>

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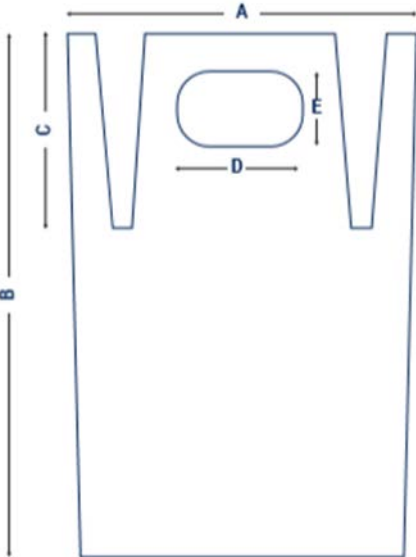
PPE Type (photos for illustration purpose only) <a href="#">[as listed in 4 nations IPC guidance]</a>	Minimum design, performance and labelling requirements. (Full compliance to chosen standard/technical solution <b>must</b> be met) ( <b>Must</b> as a minimum also collect and keep Technical Documentation)	Examples of relevant standards/reference documents to demonstrate design and performance met
<p><b>Disposable Plastic Apron</b></p> <ul style="list-style-type: none"> <li>- sleeveless</li> <li>- polyethylene</li> <li>- single use</li> <li>- non-sterile</li> </ul> 	<p><b>Design and Performance:</b></p> <ul style="list-style-type: none"> <li>• <b>Should</b> be made from low density polyethylene (LDPE).</li> <li>• <b>Must</b> not contain natural rubber latex</li> <li>• <b>Must</b> have ties that secure the apron around the body (that tie back or side not at the front where more likely to be contaminated).</li> <li>• Where made from LDPE <b>must</b> have a minimum gravimetric thickness of 16 micron (MU)/0.16 millimetres (mm) +/- 12% (BS 2782-6 Methods 631A:1994) or spot thickness of 16 micron (MU or □m)/0.16 millimetres (mm) +/- 25% OR equivalent solution/standard giving comparable performance.</li> <li>• <b>Should</b> have an impact strength of ≥30g (BS EN ISO 7765-1:2004)</li> <li>• <b>Should</b> have tear resistance ≥60mN (machine direction) (BS EN ISO 6383-2:2004)</li> </ul> <p><b>Labelling requirements:</b></p> <ul style="list-style-type: none"> <li>• The outer packaging <b>must</b> indicate the type/description of product.</li> <li>• The outer packaging <b>should</b> state the following:                             <ul style="list-style-type: none"> <li>- the material from which the apron is manufactured for example, low density polyethylene (LDPE)</li> <li>- single use</li> <li>- latex free</li> <li>- non-sterile</li> </ul> </li> </ul> <p><b>Note:</b> Specific user requirements and settings (such as wearing outdoors) may require a heavier apron.</p> <p><b>Note:</b> Any colour/opacity requirements as specified by end-user.</p>	<p>Essential Health and Safety Requirements Annex II of PPE Regulation (EU) 2016/425 – Sections 1 and 2</p>



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	<p><b>Note:</b> Typical dimensions:</p> <p>Width (A) 685 mm +/- 15mm                      Length (B) 1170mm +/- 15mm                      Tie length (C) ≥415 mm                      Neck hole width (D) ≥240mm - ≤265mm                      Neck hole depth (E) ≥160mm</p>  <p><b>Note:</b> Aprons may be provided on a roll or as a flat pack. Where provided on a roll they should be able to be torn off to allow easy dispensing, the diagram below provides an example of perforation requirements:</p> 