HM Government

v3 - 05/05/20

New High-Volume Manufacturers of COVID-19 Personal Protective Equipment (PPE) and Medical Device PPE

Essential technical requirements 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 (Table 1 and 2: *page 6 within this document*).

Notes:

Specifications already published for other types of PPE remain valid until further revisions take place. This includes for Aprons, clinical waste bags, cleaning tablets, as examples. This is a fast-moving situation and this guidance will be continually updated.

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

Who is it written by?

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

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, aprons 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 the alternative use of an existing CE marked product against the relevant legislation:

- **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 Directive 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 basic health and safety requirements (BHSR) of the PPE Directive.**

This guidance sets out the technical requirements based on what is 'minimally acceptable' for manufacturer in the context of Covid-19 threat whilst maintaining essential safety requirements and how to then apply for an exemption to the MDR or regulatory flexibilities for PPE.

This guidance does not specify the intended use of PPE, including where a medical device, once purchased by the Government against the essential technical requirements.

What must I do to ensure I meet the relevant essential requirement of safety in the absence of CE mark before I supply 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 the health and safety is the upmost priority, it is of paramount importance to ensure that the most appropriate PPE and medical devices ensuring adequate protection are swiftly made available to those who need it most during the Covid-19 threat.

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:

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020H0403&from=EN

Where market surveillance authorities find that PPE (Health and Safety Executive HSE) or medical devices (Medicines and Healthcare products Regulatory Agency MHRA) ensure 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 even though the conformity assessment procedures, including the affixing of CE marking, have not been fully finalised according to the harmonised rules they may authorise the making available of these products for supply to frontline healthcare if sourced by Government and with the caveat that they are not distributed more widely. MHRA call this exemption from devices regulation a 'derogation'.

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 to meet these essential requirements.

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

The products are therefore designed and manufactured in accordance with either:

a) a relevant harmonised European standard, or

b) any of the standards referred to in the WHO guidelines or,

c) any other non-EU standard or technical solution, provided that the specific solution ensures that the product complies with the applicable essential health and safety requirements

This approach is designed to ensure an adequate level of safety in respect to the essential safety requirements of the relevant legislation prior to an application for an authorisation to place on the UK market where a product is not CE-marked or the

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. Robust scrutiny by MHRA or HSE of the information in your application will take place before a decision is made to allow you to supply to the UK.

Purpose of the document:

This guidance sets out the essential technical and labelling requirements for these products to support meeting the criteria specified above. 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 other users other than NHS health and care workers.

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 guidance on infection prevention and control for COVID-19.

The products listed below does not mean MHRA or HSE recommends its use by health and care workers. The guidance on infection prevention and control for COVID-19 must be followed.

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

How to take Action:

Steps to take to potentially supply to the NHS in the UK for non-CE marked products or to propose the alternative use of CE marked products are supported by the User Guidance - Essential Technical Requirements for Personal Protective Equipment. This Guidance sets out the process for registering your interest to support the Government's CV-19 response including in relation to supporting evidence and the consideration and approvals process that is required of the MHRA or HSE, as appropriate. You

should only take action if you consider that you are potentially 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 the item could be used to protect both the patient and the healthcare worker the MHRA approval letter will cover the medical device regulatory consideration only. You must therefore also meet the relevant basic health and safety requirements (BHSR) of the PPE Directive. In cases of proposed dual-purpose the Regulators (HSE and MHRA) will work in partnership to ensure that the relevant authorisation/derogation is in place to enable this where the required essential technical standards are met.

Note on vocabulary

Must: Defines the essential requirement

Should: Highly desirable. As time is of the essence if omitting one of these features significantly accelerates development and production, it should be considered

Table 1: Medical device essential requirements

Medical Device	Device Type	Medical Device Essential Technical Requirements for derogation applications to the MHRA	Relevant standards for design and performance Access to harmonised and other relevant standards from BSI are free of charge
Surgical face masks	Type I - Single use/disposable (Not generally intended for use by NHS workers)	Design and Performance: • Must provide a bacterial filtration efficiency (BFE) of 95% or above to be labelled Type I if tested to BS EN 14683 • Must have differential pressure of less than 40Pa/cm^2 to be labelled Type I if tested to BS EN 14683 • Must 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.	BS EN 14683:2019 Medical face masks. Requirements and test methods or ASTM F2100 minimum Level 1

		• **Manufacturer must have quality management system in place with evidence of compliance to ISO 9001 or BS EN 13485 or equivalent** **Label: See MDR Annex I – information to be supplied with the device and use of symbols in accordance internationally recognised symbols** • **Must indicate masks type of mask. 'Type I' (if it complies with BS EN 14683) or should state 'not fluid resistant' as appropriate** • **Should have an expiry date**	**or** **equivalent technical solution**
	Type II **- Single- use /disposable**	**Design and Performance:** • **Must provide a bacterial filtration efficiency (BFE) of 98% or above to be labelled Type II if tested to BS EN 14683** • **Must have differential pressure of less than 40Pa/cm^2 to be labelled Type II if tested to BS EN 14683** • **Must 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.** • **Manufacturer must have quality management system in place with evidence of compliance to ISO 9001 or BS EN 13485 or equivalent**	

		Label: See MDR Annex I – information to be supplied with the device and use of symbols in accordance internationally recognised symbols • **Must indicate masks type. 'Type II' (if it complies with BS EN 14683) or should state 'not fluid resistant' as appropriate** • **Should have an expiry date**	
	Type IIR (Fluid resistant surgical mask (FRSM) **- Single use /disposable**	**Design and Performance:** • **Must have a splash resistance pressure of 16.0 kPa (120mm Hg) or above to be labelled Type II if tested to BS EN 14683** • **Must provide a bacterial filtration efficiency (BFE) of 98% or above to be labelled Type IIR if tested to BS EN 14683** • **Must have differential pressure of less than 60Pa/cm^2 to be labelled Type IIR if tested to BS EN 14683** • **Must 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.** • **Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485**	

		Label: See MDR Annex I – information to be supplied with the device and use of symbols in accordance internationally recognised symbols • **Must indicate type of mask. 'Type IIR' (if complies with BS EN 14683) or should state fluid or splash resistant as appropriate if equivalent test for splash resistance has been carried out** • **Should have an expiry date**	
Gloves 	**Surgical glove** **- Sterile** **- Single use/disposable** **- Powder-free**	**Design and Performance:** • **Must be made of well-established materials for this product area such as polyisoprene, polychloroprene, nitrile, latex or neoprene.** • **Must be validated as sterile – with Sterility Assurance Level (SAL) of 10^{-6}** • **Should have long cuffs, reaching well above the wrist** • **Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485** **Label: See MDR Annex I – information to be supplied with the device and use of symbols in accordance internationally recognised symbols** • **Must be labelled STERILE along with the method of sterilisation** • **Gloves containing latex must be labelled with the symbol for latex on at least the smallest packaging unit and caution**	**BS EN 455-1:2000 Requirements and testing for freedom from holes.** **or** **BS EN ISO 374-2 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration.** **BS EN 455-2:2015 Requirements and testing for physical properties.**

		placed in the instructions for use against its use where there is a known allergy to latex. • Must have an expiry date • Must specify the size	BS EN 455-3:2015 Requirements and testing for biological evaluation. (In terms of sensitivity for the wearer e.g. latex protein) BS EN 455-4:2009 Requirements and testing for service life determination. or ANSI/ISEA 105 or ASTM D6319 and BS EN 556-1:2001 for terminally sterilised medical devices for sterility aspect (where applicable)
	Examination glove - Single use/disposable - Sterile or Non- Sterile - Powder-free	Design and Performance: • Must be made of well-established materials for this product area such as nitrile, vinyl or latex • Should have long cuffs, reaching well above the wrist Label: See MDR Annex I – information to be supplied with the device and use of symbols in accordance internationally recognised symbols • Where applicable, must be labelled STERILE along with the method of sterilisation • Gloves containing latex must be labelled with the symbol for 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 latex. • Must have an expiry date • Must specify the size	

			or equivalent technical solutions
Gowns[1] 	**Surgical gown** **- Sterile** **- Single use/ disposable** **- Can include thumb-loop or cuffed gowns**	**Design and Performance:** • **Should be made of well-established materials for this product area which have considered flammability properties** • **Must be validated as sterile – with Sterility Assurance Level (SAL) of 10^{-6}** • **Made of recognised materials for this product area which have considered flammability** • **The length must be mid-calf** • **Should have bonded seams** • **Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485** **High Performance gowns** • **Hydrostatic pressure requirements (Liquid penetration): must be 100cm H_2O or above if tested to BS EN 13795.** **Standard Performance gowns** • **Hydrostatic pressure requirements (Liquid penetration): must be 20cm H_2O or above if tested to BS EN 13795.**	**BS EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods** **or** **AAMI PB70 (all levels accepted or equivalent)** **and BS EN 556-1:2001 for terminally sterilised medical devices (where applicable)** **or equivalent technical solutions**

[1] 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.

		Label: See MDR Annex I – information to be supplied with the device and use of symbols in accordance internationally recognised symbols • **Must be labelled STERILE along with the method of sterilisation** • **Must state the type of gown** • **Must address the level of fluid resistance of the gown** • **Should have an expiry date** • **Must include warnings on its use in certain areas (flammability) where appropriate**	
	Surgical gown **- Non-sterile** **- Single use/disposable** **Or** **Reusable (in line with the manufacturer's intended use**	**Design and Performance:** • **Should be made of made of well-established materials for this product area which have considered flammability properties** • **The length must be mid-calf** • **Should have bonded seams** • **Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or EN 13485** **High Performance gowns** • **Hydrostatic pressure requirements (Liquid penetration): must be 100cm H_2O or above if tested to BS EN 13795.**	

	and instructions) **Can include thumb-loop or cuffed gowns**	**Standard Performance gowns** • **Hydrostatic pressure requirements (Liquid penetration): must be 20cm H_2O or above if tested to BS EN 13795.** **Label: See MDR Annex I – information to be supplied with the device and use of symbols in accordance internationally recognised symbols** • **Must state the type of gown** • **Must address the level of fluid resistance of the gown** • **Should have expiry date** • **Must 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 Health Technical Memorandum 01-04 Decontamination of linen for health and social care (an industrial laundry cycle that achieves 71°C for 3 minutes)** • **Must include warnings on its use in certain areas (flammability) where appropriate**	

Surgical Scrubs[2] 	**Reusable (in line with the manufacturer's intended use and instructions)**	**Design and Performance:** • **Should be woven – material known to not cause irritation on the skin** **Label: See MDR Annex I – information to be supplied with the device and use of symbols in accordance internationally recognised symbols** • **Must provide reprocessing instructions. They should be compatible with healthcare laundry wash processes specified in Health Technical Memorandum 01-04 Decontamination of linen for health and social care (an industrial laundry cycle that achieves 71°C for 3 minutes)**	**WHO Guidance on Scrubs can be found on page 4**

[2] Surgical scrubs are working garments for operating room and other healthcare staff that does not need to meet the requirements for a clean air suit to BS EN 13795-2. It is not primarily intended to prevent airborne dispersal from staff and can be designed and processed as the manufacturer thinks fit. Therefore, the MHRA is not aware of a technical standard for surgical scrubs. Please refer to World Health Organisation (WHO) guidance

Table 2: Personal Protective Equipment essential requirements

Personal Protective Equipment (PPE)	Type	PPE Essential Technical Requirements for authorisation applications to the Health and Safety Executive	Relevant standards for design and performance Access to harmonised and other relevant standards from BSI are free of charge
Disposable half mask respirators	FFP3 valved FFP3 unvalved 	Design and Performance: • Mask covers the nose and mouth and the chin and may have inhalation and/or exhalation valve(s). The mask consists entirely or substantially of filter material. • Should have 2 elastic straps (may be adjustable) that go around the head and neck • Shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use. • Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485.	BS EN 149:2001+A1:2009 Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking. OR Technical Specification to satisfy the requirements of Annex II of PPE Regulation (EU) 2016/425
	FFP2 valved	Design and Performance:	

	FFP2 unvalved 	• **Mask covers the nose and mouth and the chin and may have inhalation and/or exhalation valve(s). The mask consists entirely or substantially of filter material.** • **Should have 2 elastic straps (may be adjustable) that go around the head and neck** • **Shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.** • **Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485.**	
Re-usable half mask respirator – particle filter	**Re-usable half mask respirator – with P3 particle filter** 	**Design and Performance:** • **Mask covers the nose and mouth and the chin and has one or more replaceable P3 particle filters.** • **Should have adjustable straps that go around the head and neck.** • **Shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.** • **Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485.**	**BS EN 140:1999 Respiratory protective devices – Half masks and quarters masks - Requirements, testing, marking.** **BS EN 143:2000 Respiratory protective devices – Particle filters - Requirements, testing, marking.**

		Note: P3 filters are separate consumable and must be compatible with the model of respirator. This will usually be stated on the information provided with the mask/filter. **Marking and Packaging Requirements: as specified in BS EN 140:2001 and BS EN 143:2000** **Manufacturer's Instructions and Information to be provided: as specified in BS EN 140:2001 and BS EN 143:2000**	**OR** **Technical Specification to satisfy the requirements of Annex II of PPE Regulation (EU) 2016/425**
Powered Respirators with hoods/helmets (aka Powered air purifying Respirators; PAPR)	**Powered Respirator with hoods/helmet – with P3 particle filters.**	**Design and Performance:** • **Rechargeable battery powered respirator with a hood or helmet and one or more replaceable P3 particle filters.** • **Shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.** • **Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485.** **Note: P3 filters are separate consumable and must be compatible with the model of respirator. This will usually**	**BS EN 12941 Respiratory protective devices - Powered filtering devices incorporating a loose-fitting respiratory interface - Requirements, testing, marking.** **OR**

		be stated on the information provided with the mask/filter. **Marking and Packaging Requirements: as specified in BS EN 12941** **Manufacturer's Instructions and Information to be provided: as specified in BS EN 12941**	**Technical Specification to satisfy the requirements of Annex II of PPE Regulation (EU) 2016/425**
Eye Protection	**Face shield or visor**  **Eye shields/safety glasses/goggles**	**Design and Performance:** **A face shield or visor is a device worn on the head for covering the whole of the face and providing a barrier to liquid splashes.** **All face shields/visors must comply with the following:** • **Must be optically clear.** • **Should be resistant to fogging.** • **Adjustable head band** • **Must be resistant to droplets and splashes.** **Eye Shields/safety glasses are devices for protecting the eyes against exposure to liquid droplets. All safety glasses must comply with the following:** • **Must be optically clear.**	**BS EN 166:2002 Personal eye protection** **OR** **Technical Specification to satisfy the requirements of Annex II of PPE Regulation (EU) 2016/425**

		• **Should be resistant to fogging.** • **Must be resistant to droplets and splashes.** **Marking and Packaging Requirements: as specified in BS EN 166:2002** **Manufacturer's Instructions and Information to be provided: as appropriate and as specified in BS EN 166:2002** **Note: if re-usable manufacturer should provide specific instructions for cleaning and disinfection.**	

Isolation Gowns (non-sterile/surgical)	**Isolation gown - Single use/ disposable** 	**Design and Performance:** • **Should be made of well-established materials for this product area** • **The length must be mid-calf** • **Should have bonded seams unless not required for proposed non-surgical use** • **Should have resistance to penetration by liquids** • **Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485** **High Performance gowns** • **Protective performance against liquid hazards** • **Type PB[4]-B** **Standard Performance gowns** • **For use in areas of light splashing and aerosols** • **Limited protective performance against liquid hazards** • **Type PB[6]-B** **Labelling and packaging information:** • **Must state the type of gown.**	**BS EN 14605:2005+A1: 2009 (Type 4 – spray tight)** **OR** **BS EN 13034:2005 +A1:2009– (Type 6 suits - protection against liquid chemicals)** **AND** **EN14126 (barrier to infective agents = B) Including ISO 16604 minimum level 2** **Technical Specification Technical Specification to satisfy the requirements of Annex II of PPE Regulation (EU) 2016/425**

		• **Must address the level of fluid resistance of the gown.** • **Must include warnings on its use in certain areas (flammability) where appropriate.**	

Coveralls	**Cat III Type 5B/6B Coverall** 	**Design and Performance:** • **Should be made of well-established materials for this product area.** • **Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485.** **Labelling and packaging information:** • **Must state the type of coverall.** • **Must include warnings on its use in certain areas (flammability) where appropriate.**	**BS EN 13034:2005 +A1:2009– (Type 6 suits - protection against liquid chemicals)** **EN14126 (barrier to infective agents = B)** **Technical Specification Technical Specification to satisfy the requirements of Annex II of PPE Regulation (EU) 2016/425**
	Cat III Type 4B Coverall	**Design and Performance:** • **Should be made of well-established materials for this product area** • **Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485.** **Labelling and packaging information:** • **Must state the type of coverall** • **Must include warnings on its use in certain areas (flammability) where appropriate.**	**BS EN 14605:2005+A1: 2009 (Type 4 – spray tight)** **EN14126 (barrier to infective agents = B)** **Technical Specification Technical Specification to satisfy the**

			**requirements of Annex II of PPE Regulation (EU) 2016/425**