Office for Product Safety & Standards

COVID-19 – Face Masks and Coverings

An Enforcement Guide for Trading Standards Services in Great Britain and Environmental Health Services in Northern Ireland

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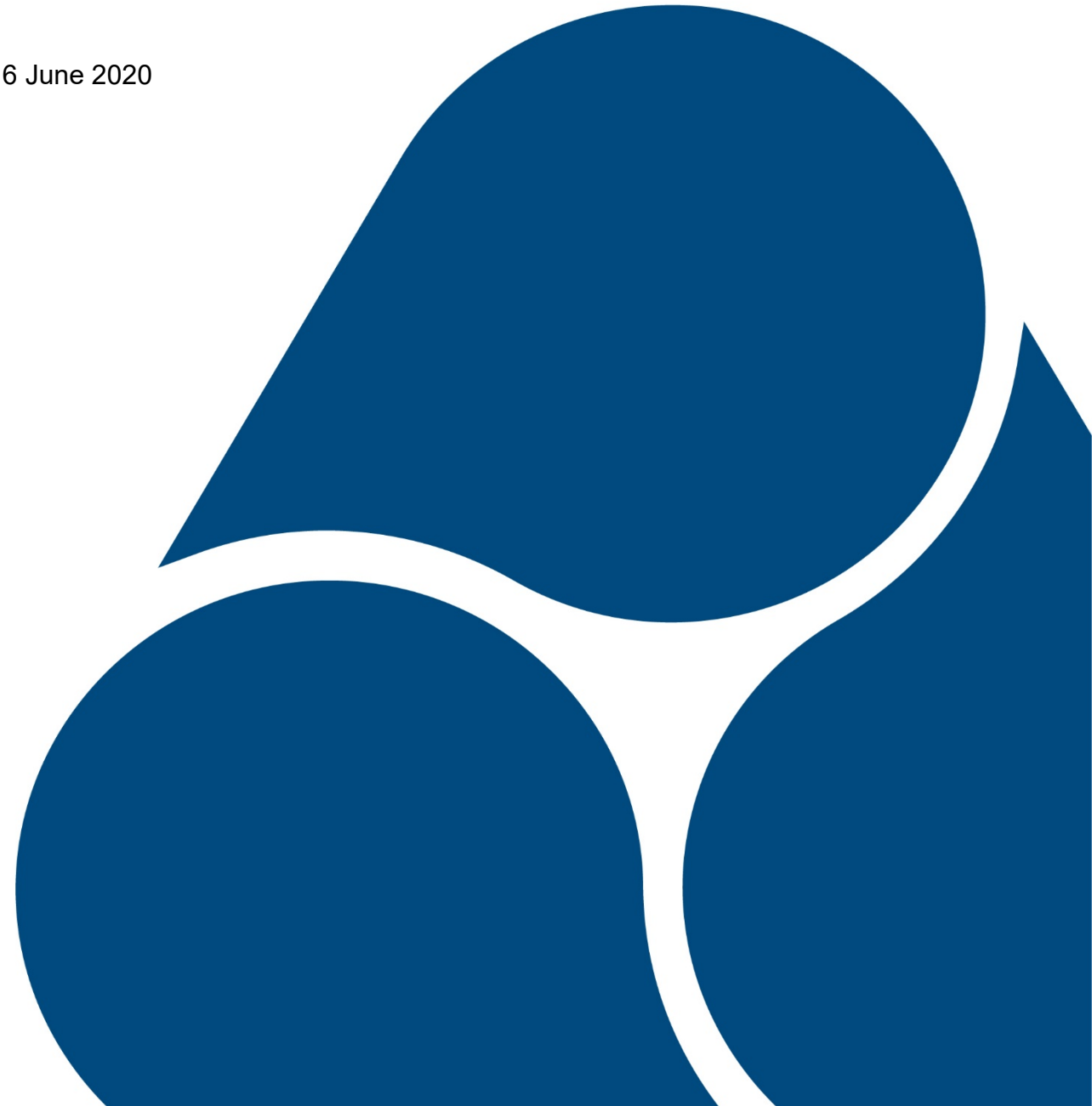


Contents

1 Introduction

1.1 This guide is designed to assist local authorities in carrying out regulatory activities relating to face masks and face coverings that are being manufactured, imported and supplied in response to the current Coronavirus (COVID-19) pandemic. It does not include information on the use of such products by members of the public or in the workplace.

1.2 This guide is relevant to face masks that are regulated under Personal Protective Equipment (PPE), and Medical Devices (MD) legislation and face coverings regulated under the General Product Safety Regulations 2005. It should be read alongside the relevant legislation and guidance that has been published to assist businesses during the pandemic which is available on GOV.UK.

Read COVID-19 guidance for businesses from OPSS.

1.3 This guide is divided into four sections. The first three sections cover the three different categories of products, as follows:

a) Face masks that are designed to protect the wearer, and are subject to the requirements of the PPE regulations;

b) Surgical face masks, that are intended to protect others (the patient) from the wearer and are subject to the requirements set out in the Medical Devices regulations; and

c) General purpose face coverings, that are not PPE or Medical Devices, these are regulated by the General Product Safety Regulations.

1.4 The final section sets out practical checks and actions that local authorities can consider when dealing with products in any of the three categories mentioned above.

2 PPE regulations

Regulations: Definition and Categories of PPE

2.1 The manufacture, importation and distribution of PPE is regulated by product safety legislation. The relevant legislation is EU Regulation 2016/425 on Personal Protective Equipment (the PPE Regulation). PPE must meet the essential health and safety requirements that are set out in Annex II of the PPE Regulation.

2.2 PPE is defined by the regulations as "equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety; interchangeable components for this equipment, or connection systems that are not held or worn but are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use."

2.3 The regulations establish three categories of PPE, based on the severity of hazard that the equipment offers protection from, rather than the complexity of the PPE itself. These categories are:

a) **Category 1:** PPE that protects from simple or minimal risks, these are listed in Annex 1 of the Regulations. Manufacturers are able to self-declare conformity. Examples of this category include items such as sunglasses and washing up gloves.

b) **Category 2:** PPE that does not fall into categories 1 or 3. These products requires 'type approval' by a notified body, and manufacturers are able to self-declare on production control. The notified body number is not required on the product. Examples of this category include high visibility jackets, bicycle helmets, hardhats and oven gloves.

c) **Category 3:** PPE where the hazard may cause serious harm to the health and safety of the user and includes hazards such as biological agents as listed in Annex 1 of the PPE Regulation. Products must normally be 'type approved' and the production control system must be reviewed by a notified body, either through audit or sample testing. Examples of this category include items such as respirator masks and life jackets. **All PPE for specific use to protect against the risk of COVID-19 including respiratory face masks, is category 3 PPE.**

Enforcement: market surveillance responsibilities

2.4 EU Regulation 2016/425 is enforced in the UK by authorities identified in the Personal Protective Equipment (Enforcement) Regulations 2018.

2.5 Where PPE is designed and/or intended for use in the workplace (i.e. non-domestic premises), by workers or others, the market surveillance authority (MSA) is the Health and Safety Executive (HSE) in Great Britain and the Health and Safety Executive for Northern Ireland (HSENI) in Northern Ireland. HSE is also the MSA where equipment is made available for use in non-domestic premises other than workplaces. The Office for Nuclear Regulation is the MSA for nuclear sites. The Secretary of State is designated as an 'enforcing authority' for the purposes of the PPE Regulations relating to all products and exercises these powers through the Office for Product Safety and Standards.

2.6 Where PPE is for private use or consumption (i.e. consumer use) the MSA is the local weights and measures authority in Great Britain (i.e. Trading Standards), and the District Council in Northern Ireland (i.e. Environmental Health).

2.7 It is therefore possible that some PPE which comes to the attention of local authority officers will be products where HSE is the MSA or OPSS can act as the 'enforcing authority'. Officers can refer matters to the HSE through the usual route, in Great Britain the HSE Safety Unit email address: safety.unit@hse.gov.uk. HSENI can be contacted at: mail@hseni.gov.uk. Where PPE for both workplace and private use, local authority officers should work with HSE or HSENI to establish who should act as the MSA.

PPE in the context of COVID-19: easements

2.8 The Government has put in place two regulatory easements in relation to COVID-19 PPE from the requirements set out in Regulation EU 2016/425 and issued revised guidance on PPE within the context of COVID-19.

Read guidance on the PPE Regulations, for new large-scale manufacturers of PPE and for small-scale manufacturers of PPE from OPSS.

2.9 For a limited time, to speed up supply of essential equipment, COVID-19 related PPE can be placed on the market before it has completed conformity assessment procedures, provided it meets essential health and safety requirements in line with Regulation EU 2016/425. However, manufacturers **must** have contacted a notified body and have begun conformity assessment. The notified body must be in a position to support the claim that the product meets the essential health and safety requirements.

2.10 The second easement, also for a limited time, is that any COVID-19 related PPE that is being procured by the Government/NHS for use by healthcare workers does not need to be conformity assessed, providing it has been manufactured either in line with a relevant European Standard, in accordance with a standard referenced in the WHO guidelines or to an alternative technical solution that delivers adequate safety. Equipment procured in this way will be assessed by the MSA, the Health and Safety Executive, against the essential health and safety requirements to ensure it is safe and effective. PPE procured in this way must be offered through the official channels, with contact made through the GOV.UK webform. This route is best suited to large-scale manufacturers.

2.11 PPE assessed as complying with a relevant EU harmonised standards has a presumption of conformity with the essential health and safety requirements set out in the Regulations. In line with the easement described above, products on the UK market may reference other technical solutions such as standards for other parts of the world provided they ensure an equivalent level of protection to meet the essential health and safety requirements.

2.12 Where this is the case, the PPE regulations still apply, with the easements described above, and the product would have to either be undergoing conformity assessment by a notified body who will attest that it meets the essential health and safety requirements, or is being purchase by the UK Government through the GOV.UK webform.

Application of regulations to small businesses and donated PPE

2.13 Within the context of COVID-19, small businesses, individuals, and organisations such as charities and schools are offering PPE for donation or sale. This includes ‘home made’ sewn or 3D printed PPE for both workplace and personal use. If such equipment is intended to provide protection and is PPE, it is subject to the same regulations and market surveillance activities as PPE imported and manufactured in any other way.

Read guidance for small-scale manufacturers of PPE from OPSS.

3 Medical devices

Medical devices and PPE

3.1 Some types of products that appear to be like PPE may actually be regulated as medical devices if their intended purpose is to protect others from the user (like a surgical face mask). A face mask is a medical device if its intended purpose is to protect the patient from the doctor. If its intended purpose is to protect the doctor from the patient, it is PPE.

3.2 Medical devices are regulated by the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002.

Read guidance on the regulation and safety of medical devices from MHRA.

Enforcement

3.3 In most cases, the Medicines and Healthcare products Regulatory Agency (MHRA) is the MSA for products regulated under the Medical Devices Regulations. However, there is a duty on local weights and measures authorities in Great Britain and each district council in Northern Ireland to enforce the Medical Device Regulations 2002 for devices that are consumer goods, in conjunction with the Secretary of State.

3.4 In the context of COVID-19, Class I medical devices could include surgical facemasks and examination gloves. It is unlikely that these would be consumer goods, and therefore more likely that the MHRA will have enforcement responsibility for these types of products. More information about medical devices within the COVID-19 context is provided on GOV.UK.

Read guidance about medical devices in the COVID-19 context from MHRA.

3.5 Officers can contact MHRA through the usual route devices.compliance@mhra.gov.uk

Borderline products

3.6 For some products, it may be difficult to assess if the product should be considered a medical device within the terms of the Medical Devices Directive. The MHRA has produced guidance for these instances.

Read guidance on borderline products from MHRA.

4 Face coverings

4.1 The Government has advised the public to consider wearing face coverings in some circumstances to help reduce the spread of coronavirus.

4.2 An increasing range and quantity of products designed to cover a person's mouth and nose are being produced and supplied. Where these products are not supplied as PPE or medical device face masks, their safe production and supply is regulated by The General Product Safety Regulations 2005 (GPSR).

4.3 Guidance for manufacturers and makers of face coverings setting out their obligations under GPSR and support to assist in the assessment of the safety of these products is available on GOV.UK.

Read guidance on face coverings from OPSS.

Descriptions and disclaimers

4.4 A product, that has not been designed or manufactured to comply with essential requirements of the PPE or Medical Devices legislation, does not become PPE or a medical device if a business in the supply chain (that was not involved in the design or manufacture of the product), states, suggests or implies the product provides protection. In such cases consideration should be given to the Consumer Protection from Unfair Trading Regulations 2008.

4.5 Where a product designed or manufactured as PPE or as a medical device is found to be non-compliant, the business in the supply chain that owns it can take on producer responsibility and repurpose it to sell as a face covering if the business can demonstrate it meets the requirements under GPSR. In this case the CE mark and any claims or references to meeting PPE standards (such as those in Annex 2) or claims to offer protection from particular risks must be removed from the product itself, the packaging, any accompanying paperwork and any form of advertising or marketing. The business taking producer responsibility must be able to demonstrate that the product is a safe product and add appropriate labelling to comply with GPSR.

5 Practical checks and actions to be considered for face masks and face coverings

5.1 There may be situations where local authority officers provide advice to businesses (including in their role as primary authority) or need to make checks relating to face masks and coverings, including:

a) as the MSA for PPE or medical devices, local authority officers may encounter PPE face masks or medical devices for consumer use or, where the end user of the PPE or medical device is unknown e.g. at ports or online;

b) as enforcement authority regarding face coverings for consumers under GPSR; and

c) while supporting local authority procurement team colleagues in assessing PPE, medical devices or consumer face coverings for use within their local authority (acting as a purchaser rather than MSA or enforcement authority).

5.2 This section offers advice for local authority officers on checking face masks and face coverings and is summarised in the flow chart at Annex 1. Links to additional information that may assist can be found on Regulators Companion.

PPE face masks

5.3 As outlined above, all PPE face masks for protection against COVID-19 are classified as category 3 under the relevant Regulations. Products must be 'type approved' with production control reviewed by a notified body through audit or sample testing and be CE marked, including the number of the notified body.

5.4 The regulatory easements, outlined in paragraph 2.9 above, mean non-CE marked PPE is currently allowed on the UK market if the manufacturer or importer is in the process of getting the product conformity assessed and the notified body will attest that the product meets the essential health and safety requirements. These products may be marked with indications that they are made in accordance with a standard e.g. BS EN 149 or N95 see Annex 2. In such circumstances the producer must be able to provide confirmation to you that a notified body has confirmed the essential safety requirements of the PPE Regulation have been met and, the product has been accepted into the process of conformity assessment.

5.5 PPE that is part of Government / NHS procurement for frontline healthcare workers follows a specific process and is unlikely to be seen by local authority officers.

Visual and physical checks

5.6 The officer may carry out visual checks using photographs and physical checks of products such as:

a) In accordance with EU Regulation 2016/425 the product (or where not possible the packaging or in documentation accompanying the PPE) should be clearly marked with the:

- CE mark;
- number of the notified body involved in reviewing production control;

- type, batch or serial number;
- name and address of the manufacturer; and
- importer's name and address (where relevant).

b) In addition, BS EN 149 requires:

- type identifying marking;
- the number and year of the Standard, classification, 'NR' if mask is for single shift use only and, if appropriate 'D' (Dolomite) in accordance with anti-clogging performance (or example, EN 149:2001 FFP3 NR D);
- the packaging to protect the product against mechanical damage and contamination before use;
- the parts likely to come into contact with the wearer to have no sharp edges or burrs;
- the mask to withstand cleaning and disinfection specified by the manufacturer if designed to be reusable; and
- The head harness to be designed so the mask can be donned and removed easily, and to be adjustable or self-adjusting and hold the mask firmly in position.

Documentary checks

5.7 The officer may carry out checks on documentation the producer/ distributor has for the product such as:

a) The Declaration of Conformity which must contain all relevant details of the manufacturer and other information such as the standard(s) for which compliance is being declared with.

b) The Technical File for the product (the responsibility to draw up a Technical File rests with the manufacturer).

c) EU Type Approval Certificate issued by a notified body notified under the PPE Regulation. (Type Approval Certificates tend to be short). notified body numbers can be checked here: https://ec.europa.eu/growth/tools-databases/nando/

d) Any instructions for safe use need to:

- accompany every smallest commercially available package;
- be, at least, in the official language(s) of the country of destination;
- contain information on the product's application / limitations, the meaning of any colour coding, checks prior to use, donning and removing, fitting, use, maintenance e.g. cleaning, disinfecting (if applicable), storage, the meaning of any symbols/pictograms used;
- warn against likely problems e.g. relating to fit; and
- advise on when the product should be discarded.

5.8 When examining test reports and Certificates, officers may wish to consider:

a) Do they relate to the product?

b) Do they cover the applicable Standard/ specification?

c) Are they from a notified body? If in doubt, checks can be made against intelligence sources and also information on https://eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe and https://www.bsif.co.uk/warning-fake-ppe-certificates/

Medical device face masks

5.9 Generally referred to as surgical (medical) masks, these are intended for health care staff to wear to protect patients during surgical procedures and other medical settings. They are Class I medical devices; they must meet the design and safety requirements of the Medical Devices Regulations and be CE marked. Sterile Class I medical devices require notified body approval.

5.10 In response to the COVID-19 pandemic, MHRA has introduced a derogation and may authorise manufacturers to supply a non-CE marked device in the interest of protecting health.

Read guidance on the exemption of medical devices during the COVID-19 outbreak from MHRA.

5.11 The MHRA has published advice on the requirements for Medical Device face masks. The requirements include for technical documentation e.g. description, component documentation, final produce documentation, compliance with essential requirements, clinical evaluation.

Read guidance on class 1 medical devices from MHRA.

5.12 If local authority officers encounter Medical Device face masks they can contact MHRA through the usual route devices.compliance@mhra.gov.uk.

Face masks and coverings that are not category 3 PPE or medical devices

5.13 In response to Government advice to the public about wearing face coverings an increasing range of products are available on the market.

5.14 When assessing the safety and compliance of products for use by consumers under the General Product Safety Regulations 2005, officers may wish to consider the following checks:

a) Hazards associated with this type of product including strangulation, suffocation, choking, sharp points, rough edges, chemical content.

b) Claims made on the product labelling and marketing

c) The needs of particular classes of person, especially children.

d) Traceability information: does the product or packaging have the name and address of the producer, product reference, batch number (where applicable), can the producer keep distributors informed of issues?

5.15 The producer should be able to demonstrate product they place on the market is safe. More information about this can be found on the Business Companion website.

Unsafe / non-compliant products

5.16 The product safety market surveillance framework provides a range of powers for local authorities. These are summarised in annex 3 and include powers of entry, inspection, and detention once products have been placed on the market.

5.17 Where unsafe or non-compliant product is identified, officers should take a proportionate approach and follow up in line with OPSS' letter to local authority Heads of Service, Regional Coordinators, and National Product Safety Group members concerning PPE, the Regulators' Code and their local enforcement policy.

5.18 Cases should be logged on the Product Safety Database.

5.19 Relevant intelligence (including counterfeit test certificates) should be logged on IDB; for those not operating IDB officers should email the intelligence to OPSS.Intelligence@BEIS.gov.uk.

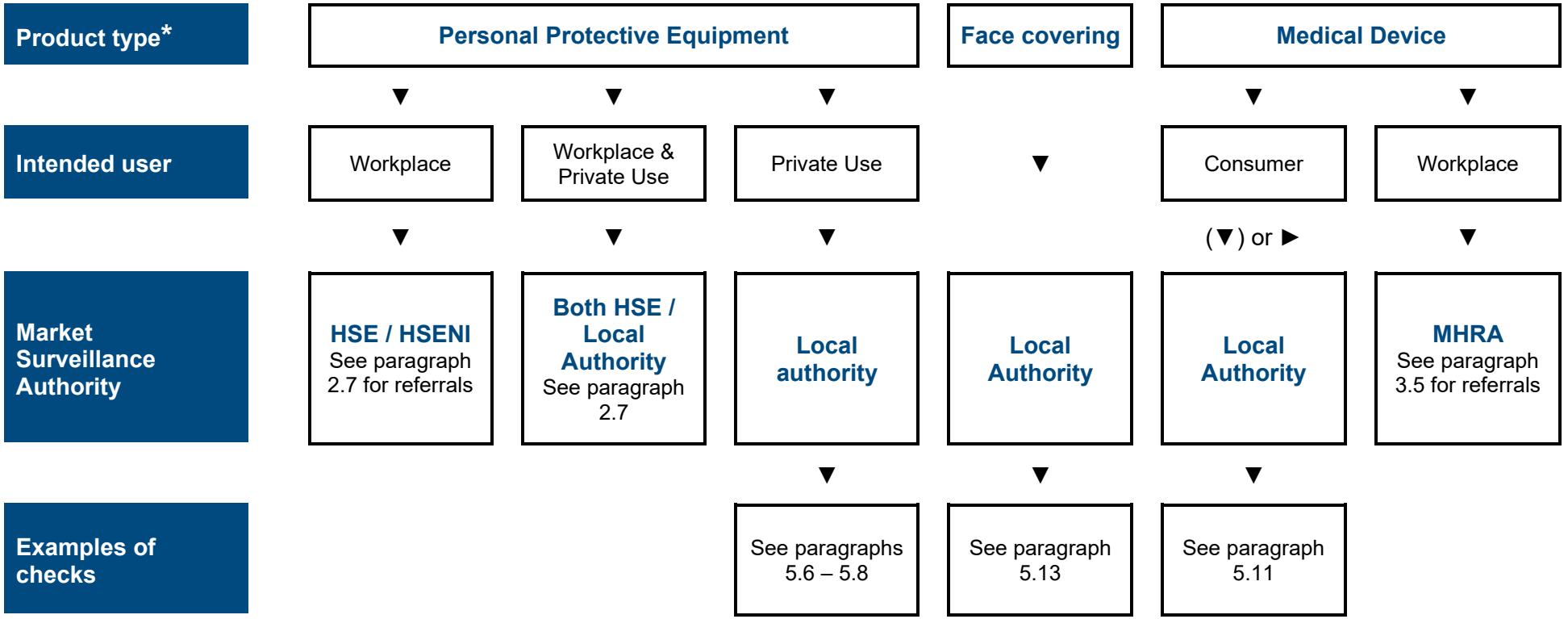
6 Support for local authorities and further information

6.1 OPSS provides peer support for local authority officers investigating complex cases. To raise queries please email OPSS.Enquiries@BEIS.gov.uk

6.2 The National Product Safety Group has members in each region and Nation of the UK. The Group is an excellent source of expertise to support interpretation of the Regulations and sharing of good practice.

6.3 A range of resources and learning opportunities to support local authority officers with product safety work is available on Regulators Companion. These resources consist of documents and links originating from a variety of organisations and have been collated as information that may assist TS and EHNI. They do not form part of this Guide.

Annex 1 – Flow chart



*In determining product type, consider labelling and marking of the product and packaging, any claims being made and any documentation.

Annex 2 – Relevant PPE and Medical Device standards

In the context of the current COVID-19 pandemic, BSI has made a series of European Standards (ENs) for PPE and Medical Devices publicly available free of charge. They can be found here: https://www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/medical-devices-ppe/.

BS EN 149:2001 +A1:2009: Respiratory protective devices; specifies minimum requirements for filtering half masks as respiratory protective devices to protect against particles. There are three classes of devices: FFP1, FFP2 and FFP3. The UK recommends the use of FFP3 respirators when caring for patients where high risk aerosol generating procedures are being performed. When FFP3 are unavailable then FFP2 respirators may be used.[1]

In addition to BS EN 149, local authority officers may find face masks that claim compliance with a range of PPE standards and specifications from third countries. Producers may wish to use such standards as alternative technical solutions to harmonised standard EN 149. As part of bringing the product to the EU / UK market an appropriate notified body will check the extent to which the standard used by the producer demonstrates the essential requirements of the applicable legislation have been met. Non-EU standards commonly referenced currently are:

42CFR84: the US standard for N95 class respirators. HSE and PHE undertook a review and found no material difference between the N95 respirator and the FFP2 respirator. They provide comparable protection against coronavirus providing the wearer has passed a face fit test[2].

GB2626-2006: the Chinese standard for respirators including KN 100, KN95 and KN90. This standard sets out performance requirements that are similar to EN 149; KN 95 masks are similar to FFP2 respirators.

Other standards and specifications for respirators include:

a) Australia & New Zealand: AS/NZ 1716:2012 for P2 class respirators.

b) Korea: KMOEL - 2017-64 for 1st class respirators.

c) Japan: JMHLW Notification 214, 2018 for DS class respirators.

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1 https://www.hse.gov.uk/news/face-mask-equivalence-aprons-gowns-eye-protection-coronavirus.htm

2 https://www.hse.gov.uk/news/face-mask-equivalence-aprons-gowns-eye-protection-coronavirus.htm

Annex 3 – Powers

Once a face mask or covering has been placed on to the market, a range of enforcement powers are available to local authorities:

PPE face mask enforcement powers:

The Consumer Rights Act 2015, Section 77, Schedule 5, Part 4
The Personal Protective Equipment Regulations 2018, Regulation 5
The Personal Protective Equipment (Enforcement) Regulations 2018, Schedule 1 under The Consumer Protection Act 1987

Medical device face mask

The Consumer Rights Act 2015, Section 77, Schedule 5, Part 4
The Medical Devices Regulations 2002, Regulation 62 under The Consumer Protection Act 1987

Face covering

The Consumer Rights Act 2015, Section 77, Schedule 5, Part 4
The General Product Safety Regulations 2005

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