



Office for Product
Safety & Standards

Guidance for manufacturers and makers of face coverings to comply with the General Product Safety Regulations 2005

Version 6

This guidance does not introduce new rules or burdens but sets out the legal requirements that have been in place since 2005, to ensure products are safe when placed on the market.

Who is this guidance for?

This guidance is designed to help businesses (large or small), organisations or individuals who may want to make for sale, cloth face coverings which are regulated under the existing General Products Safety Regulations 2005. This guidance does not relate to the manufacture of Personal Protective Equipment, as explained separately below.

The Cabinet Office and the Department for Health and Social Care have published guidance on [face coverings: when to wear one and how to make your own](#)

[Read guidance on how to make a cloth face covering](#) from the UK Health Security Agency.

[Read guidance on face coverings](#) from the World Health Organisation.

Is a face covering PPE or a medical device?

Cloth face coverings are generally not Personal Protective Equipment (PPE) or a medical device and should not be sold or donated as PPE or Medical Devices. If they are sold or donated as PPE or Medical Devices, they must comply with the PPE or Medical Devices regulations (see below for further detail).

Cloth face coverings which are sold or donated with particulate material 2.5 filters or other hygiene filters, should not claim to give protection against COVID-19, or they will need to comply with the PPE Regulations.

If a biocide has been applied to the cloth, or cloth face covering, a manufacturer in Great Britain must comply with the Biocide Products Regulation 528/2012, as amended to apply in Great Britain. If the manufacturer is in Northern Ireland, they must comply with the EU Biocide Products Regulation 528/2012.

[Find information on biocides from the Health and Safety Executive.](#)

[Read guidance on the PPE Regulations](#) from the Office for Product Safety and Standards.

If you want to manufacture and sell/ donate Medical Devices, your product must comply with the Medical Devices Regulations.

[Read guidance on the Medical Devices Regulations](#) from the Medicines and Healthcare products Regulatory Agency.

If your product is both PPE and a Medical Device, it must comply with both sets of Regulations.

If you want to sell face coverings

If you want to sell face coverings, the product must meet the existing requirements of the [General Product Safety Regulations 2005](#). This legislation requires that only **safe** products may be placed on the market.

A safe product is one which, under normal or reasonably foreseeable conditions of use, does not present any risk, or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons.

To make sure that a product is safe, the producer has specific obligations and must take into consideration factors detailed in the Regulations, including:

- the characteristics of the product, including what it is made of, and how it is designed and made, how it is packaged, instructions for assembly and, where applicable, instructions for use and maintenance;
- the effect of the product on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product; and
- the categories of consumers at risk when using the product, in particular children and the elderly.

To ensure face coverings are not confused with PPE or a medical device, there must be no claims to the effect that the face covering is categorised as PPE or a medical device for the purposes of product safety law. For example, there should be no claim to the effect that the face covering has been manufactured with the intention of offering protection (a) to users from risks to health and safety (whether COVID-19, pollution, pollen or dust) and/or (b) to people other than the wearer from risks to their health and safety. You can find advice on advertising from the Advertising Standards Agency here in the face coverings section: [ASA advice on coronavirus covid-19](#).

Responsibilities of those making and distributing products

The General Product Safety Regulations set out the responsibilities of the producer and distributor with regards to informing the consumer or user of the risks posed by the product and any labelling and documentation requirements.

The producer will need to demonstrate it has assessed and taken action to mitigate the risks inherent in the product throughout normal or reasonably foreseeable uses.

Labelling can be used to indicate the normal use, for example, advising on the label that the face covering should be disposed of after e.g. 50 washes, but it may be reasonably foreseeable that it is used for slightly more washes than this.

The UK Health Security Agency does not recommend face coverings for children under the age of 3 for health and safety reasons.

Assessing whether the face covering you are designing is safe

The table below outlines an example safety assessment that you could use to assess whether your face covering is safe. It is a guide, not an exhaustive list. It is your responsibility as the producer to consider all the risks associated with the specific face covering that you want to sell. In addition, the British Standards Institution has produced '[Flex 5555](#)' as a 'best practice' guide for ensuring safety of face coverings, and this is free to download. If you need more help in considering the safety risks of your product, you should contact your Local Authority Trading Standards team.

Risks	Requirements	Checks
Physical (covering / skin contact)	Face covering must not contain any sharp points or rough edges that will pierce or cut skin	Visual examination
Physical (straps)	Straps hold the face covering in place and ensure a good fit for intended user groups Straps must not cut into skin Straps must not be a strangulation hazard	Visual examination
Physical (body of covering)	Face covering must not impede the wearer from breathing (suffocation hazard) Face covering must not release small parts and the risks assessed of adorning it with potential choking hazards such as, for example, buttons, beads, sequins, or similar Face covering to be made from a fabric that does not shed fibres that may be inhaled during use, and is not covered in glitter paint Face covering not to be made from a material not designed to be worn against the skin or dyed with chemicals containing poisons that could be ingested Allergenic materials, such as latex in elastic, where worn against the skin, e.g. in head attachments, should be avoided or included in label warning on packaging and on the covering itself Any added biocide should not adversely affect human health in the short or long term	Written assurance from supplier that the fabric is suitable for use in a face mask / list of suitable fabrics in an accepted specification

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