

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

### Version 3

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 or donation, face visors for use by consumers in conjunction with a cloth face covering, and which are not designed or intended to protect the user from COVID-19. Such visors are regulated under the General Products Safety Regulations 2005

This guidance does not relate to the manufacture of Personal Protective Equipment, as explained separately below.

# Making the right claims about the face visor you are making

You must be clear about what the intended use of the visor you are selling, and it must be made in accordance with the regulations relevant to that intended use. You must not deliberately or inadvertently make claims about your visor, e.g. that it provides protection, when it does not comply with those regulations. If you do, you may be prosecuted under those regulations as well as falling foul of the Advertising Standards Authority.

If the visor you manufacture is designed to be worn or held by a person for protection against one or more risks to that person's health or safety and/or you claim as such, it will be considered PPE and must comply with Regulation 2016/425 ("the PPE Regulations"). Among other things, the PPE Regulations require you to be able to demonstrate that the product meets the essential health and safety requirements in Annex II of Regulation 2016/425. Failure to comply with the obligations in the PPE Regulations may be an offence and enforcement action may be taken.

If the visor you manufacture meets the definition of a medical device e.g. if it is designed and manufactured for protection against risks to the health and safety of a person other than the wearer (see MHRA guidance referred to below for further detail), and/or you claim as such, then the Medical Devices Regulations 2002 will apply. Failure to comply with the obligations in those Regulations may be an offence and enforcement action may be taken.

If your visor meets the definitions of both PPE and medical devices, and/or you claim as such, it must comply with both sets of Regulations.

Read guidance on the PPE Regulations from the Office for Product Safety and Standards.

Read guidance on the Medical Devices Regulations from the Medicines and Healthcare products Regulatory Agency.

In addition, if a biocide is applied to the visor, the visor must comply in Great Britain with the Biocide Products Regulation 528/2012, as amended to apply in Great Britain, and in Northern Ireland with the EU Biocide Products Regulation 528/2012. This Regulation places duties on you as the manufacturer in relation to the biocide.

Read guidance on biocides from the Health and Safety Executive.

# If you want to supply face visors as face shields and not PPE or as a medical device

https://www.gov.uk/government/publications/face-coverings-when-to-wear-one-and-how-to-make-your-own/face-coverings-when-to-wear-one-and-how-to-make-your-own

Guidance from the Department for Health and Social Care, and from the Scottish and Welsh Governments, is clear that face visors are not alternatives to face coverings. They should only be worn as face shield together with a face covering.

If you want to make or import face visors as a face shield and not as PPE or as a medical device, the product must meet the existing requirements of the <u>General Product Safety</u> <u>Regulations 2005</u>. This legislation requires that only **safe** products may be placed on the market or otherwise supplied.

To ensure face visors designed to be supplied just as a face shield are not confused with PPE or a medical device, there must be no claims to the effect that the visor 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 visor has been manufactured with the intention of offering protection (a) to users from risks to health and safety and/or (b) for people other than the wearer. The UK Health Security Agency advises that you label the visor "This visor is not PPE".

It must be labelled with the name and address of the producer, the product reference, and batch series number if applicable.

Under the General Product Safety Regulations 2005, 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.

Instructions for use for re-usable visors should advise users of the need for proper cleaning/ disinfecting after each use.

## Responsibilities of those making and distributing products

The General Product Safety Regulations 2005 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.

For example, 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, disposal after the visor no longer provides clear visibility. It should also be used to give any warnings on limitations on use, for example that face visors should not be worn by children under 36 months.

## Assessing whether the face visor you are designing is safe

The table below outlines an example safety assessment that you could use to assess whether your visor 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. If you need more help in considering the safety risks of your product, you should contact your Local Authority Trading Standards team.

FACE VISORS		
Risks	Requirements	Checks
Sharp edges	Visor must not have any sharp points or rough edges that will pierce or cut skin	Visual examination
Body of visor	Visor must provide clear visibility and be fogresistant  Visor must completely cover the sides and length of the face (i.e. to below the chin)  Visor must protect the eyes, nose and mouth from splashes  Visor must not impede the wearer from breathing (suffocation hazard)  Visor 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  Visor must not to be made from a material not designed to be worn against the skin or releases toxic chemicals during normal activity	Written assurance from supplier that the material is suitable for use in a visor / list of suitable materials in an accepted specification
	Visor not to be readily flammable  Any added biocide should not affect human health adversely in the short or long term	

Headband	Headband holds the visor in place and ensure a good fit for intended user groups	Visual examination
	Headband must not cut into skin	
	Headband must be minimum of 10 mm thickness	

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