Guidelines: Mouth and Nose Masks

FAQ

As at: 09/04/2020

1. What is the difference between protective masks and mouth and nose masks?

Masks that are intended to cover part of the face, in particular the mouth and nose of the wearer, may be made available on the market either as **protective masks** or **items of clothing** (so-called mouth and nose masks). The categorisation is based on the intended purpose or use.

1.1 What are protective masks?

With protective masks the emphasis is on the **protective function**. Depending on the protection objectives, protective masks may categorised as a **medical device** (medical face masks, also called surgical masks) or respiratory protective devices classed as **personal protective equipment (PPE)**, in particular particle filtering half masks (**"filtering facepieces" – FFP**).

In the EU, medical devices or PPE are only allowed to be placed on the market if they meet the requirements of the **Medical Devices Directive 93/42/EEC** or the **PPE Regulation (EU) 2016/425**. In particular, they must bear a CE marking which indicates that the product conforms with the applicable legislation.

1.2 What are medical face masks?

Medical face masks (also called surgical masks) are classified as medical devices and are worn by employees in the healthcare system (doctors, nurses etc.) in order to protect patients from (potentially infectious) droplets of mucus or saliva coming from the employee's the mouth or nose. To this extent there is a **medical intended purpose**. In addition, medical face masks may also protect the mouth and the nasal mucous membrane of the wearer against larger droplets in the sputum of the patient or touching contaminated hands (contact infection).

1.3 What requirements must medical face masks fulfil?

In general, medical face masks must meet the requirements of the **European Medical Devices Directive 93/42/EEC** and its national implementing legislation as well as the **European Standard EN 14683** ("Medical face masks - Requirements and test methods"). The current German version of this standard can be accessed free of charge on the website of Beuth Verlag (www.beuth.de).

Further information about the European Medical Devices Directive can be found in "Guidelines to EU Directive 93/42/EEC" ("Merkblatt zur EU-Richtlinie 93/42/EWG", only available in German) from the Bavarian Ministry of Economic Affairs (https://www.stmwi.bayern.de/fileadmin/user_upload/stmwi/Publikationen/2019/2019-02-14_Merkblatt_-_Medizinprodukte.pdf).

1.4 What are particle filtering half masks (FFP masks)?

Medical face masks are neither designed nor intended to protect the wearer against viruses and other contaminants in the environment which are transmitted by air. Respiratory protective devices such as **particle filtering half masks (FFP masks),** in particular, are required for this as respiratory protection is used against infectious aerosols. FFP masks are covered by the European PPE Regulation (see questions 1.1 and 1.5).

1.5 What requirements must FFP masks fulfil?

FFP masks must meet the requirements of the **European PPE Regulation (EU) 2016/425** and the **European Standard EN 149** (Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking) when made available on the European market. The European PPE Regulation applies directly in all EU member states.

European Standard EN 149 classifies FFP masks according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices: FFP1, FFP2 and FFP3. FFP1 masks have the lowest level of performance, while FFP3 masks provide the highest protection. The protection provided by an FFP2 or FFP3 mask includes that provided by devices in lower classes.

The current version of the DIN EN 149 standard can be accessed free of charge on the website of Beuth Verlag in German and/or English (www.beuth.de).

Further information about the usage and marketing of FFP masks can be found on the FAQ page of the Federal Institute for Occupational Safety & Health (BAuA) (only available in German) (https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-Betrieb/Biostoffe/FAQ-PSA/FAQ_node.html).

2. What are mouth and nose masks? How are they different from protective masks?

Masks which are placed on the market as (reusable) **items of clothing** (“mouth and nose masks”) must be distinguished from protective masks (see question 1.1).

Mouth and nose masks do not have a medical intended purpose and are not placed on the market as personal protective equipment which has been developed or manufactured as respiratory protection against contaminants. Mouth and nose masks are therefore not allowed to bear a CE marking (also see question 1.1).

2.1 What protection can mouth and nose masks provide?

All items of clothing may provide a certain (physiological) **protective function** (e.g. protection against cold or wet conditions). In that sense, the European PPE Regulation (EU) 2016/425 expressly states that personal protective equipment designed for private use to protect against non-extreme weather conditions (rain, wind etc.) does not fall under the Regulation.

Mouth and nose masks may also offer a certain protective function. They can form a physical barrier to reduce the spread of larger droplets resulting from coughing, for example, and/or contact infection (such as touching the mouth and the nasal mucous membrane with contaminated fingers) when used correctly and made of the correct material (similar to medical face masks).

This barrier function, however, does not change the intended purpose of the mouth and nose mask, i.e. its function as clothing. This means that mouth and nose masks are merely items of clothing and are not protective equipment (also see question 2).

2.2 What is important when advertising mouth and nose masks?

When advertising mouth and nose masks it is important to ensure that it does not contain any untrue or misleading information. This includes, in particular, statements which could imply that the mask is a medical face mask, a respiratory protective device (FFP mask) or other comparable protective equipment. This type of impression may arise, for example, from advertising statements like “Priority supply to hospitals and care facilities” or using images of medical facilities in advertising.

Particular care must be taken with descriptions and claims that suggest a particular protective function, in particular protection against health risks and/or with names that are usually used for protective equipment or medical devices such as “respiratory protective device”, “medical face mask” or “surgical mask”.

Manufacturers and other economic operators are recommended to **specifically clarify** that the mouth and nose masks offered are not medical devices or personal protective equipment (PPE) and in this respect are not intended for use by healthcare staff, for occupational safety or as other equipment to protect against infection or other contaminants.

Examples:

(English)

This mask is intended for private use only. It is not certified as a medical device or personal protective equipment. It is not intended for use by healthcare staff, for occupational safety or as other protective device to protect against infection or other contaminants. Please read the product information and instructions before use.

(German)

Nur für die private Verwendung bestimmt. Kein Medizinprodukt oder persönliche Schutzausrüstung. Nicht für den Einsatz im Gesundheits- oder Pflegewesen, als Arbeitsschutz oder sonstige Schutzausrüstung zum Schutz vor Infektionen oder anderen Schadstoffen geeignet. Vor Gebrauch die weiteren Produkt- und Gebrauchsinformationen lesen.

2.3 Which product legislation should be particularly considered when providing mouth and nose masks?

Mouth and nose masks do not fall under the European Medical Devices Directive or the European PPE Regulation (also see questions 2. and 2.1). They therefore do not bear a CE

marking. However, there are other product, fabric and sales related legislation to consider, in particular:

- The Textiles Labelling Regulation (EU) 1007/2011
- The REACH Regulation (EU) 1907/2006
- Unfair competition legislation (German Act against Unfair Competition (UWG) and German Act on the Advertising of Medical Products (HWG))
- The General Product Safety Directive and the German Product Safety Act (ProdSG)
- If applicable, the Biocides Regulation (EU) 528/2012 (if the product is treated with/with added biocidal product(s) and/or supplied with information about biocidal properties, e.g. anti-microbial)

With the exception of disposable (non-reusable) products, mouth and nose masks must be labelled or marked to show their fibre composition in accordance with the European Textile Regulation whenever they are made available on the market. In most cases, however, it is sufficient to provide the information on the product packaging (see question 2.5).

Further information on the European Textile Regulation is available in the "Textile labelling/marking Guidelines" produced by textile+mode (only available in German) (https://textil-mode.de/de/newsroom/blog/textilkennzeichnung/).

2.4 What applies with regard to product safety and product liability? What should be specifically pointed out to consumers and other end-users?

Product safety requirements result from the General Product Safety Directive 2001/95/EC and the German Product Safety Act (ProdSG). Furthermore, manufacturers must also consider **product liability** legislation which applies to unsafe products.

Manufacturers should therefore provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without warnings, and to take precautions against those risks. The legislation on product safety and liability sets particularly strict standards where there is a risk of damage to health.

Mouth and nose masks can quickly become contaminated with potentially infectious droplets and other materials (both inside and outside). In addition, it is also possible that consumers (mis)use the mask in such a way which could risk their health, or that of others, for example, because of incorrect care or improper use as a protective device. For this reason, corresponding **warnings and usage instructions** for consumers are essential (see question 2.5).

The following **information and labels** should be particularly considered:

<u>Warning information / usage instructions:</u>

- Information that the mask is not a medical device or personal protective equipment (see example in question 2.5).

- Information that the mask is intended for private use only and, in particular, is not designed to be protective equipment to protect against infection and other contaminants or for use in healthcare or for occupational safety (see example in question 2.5).

- Instructions how to correctly put on (e.g. only over the mouth and the nose) or remove the mask.

- Information that the mask should be removed and replaced when it becomes wet or damp.

- Information that used masks should be either placed in an airtight container (e.g. plastic bag) to avoid contamination or washed immediately.

- Information that hands (if necessary also the corresponding area of the face) should be washed with soap and/or suitable sanitiser before and after putting on or taking off the mask, or otherwise touching it.

- Care instructions such as (maximum) recommended washing temperature or, if applicable, maximum number of washes. These instructions may be alternatively provided on a textile care label using care symbols (see “Voluntary but recommended labelling/marking” below).

Mandatory labelling / marking required by law:

- Textile labelling or marking in accordance with the European Textile Regulation (fibre composition).

- Manufacturer's identification (name and postal address of the manufacturer established in the EU or EEA) and product identification information (e.g. model and/or item number and/or GTIN).

- Information in accordance with the European Biocides Regulation, if applicable.

Voluntary but recommended labelling/marking:

- Textile care labelling or marking with language independent care symbols (see www.ginetex.de); care instructions may be alternatively provided in writing (see “Warning information / usage instructions” above).

- Size labelling, if applicable.

If the mask is worn in another way despite information/labelling to the contrary from the manufacturer then the user is ultimately **solely** responsible for this.

2.5 Where and how should the required information be indicated?

When making mouth and nose masks available to German consumers the legally required information (see questions 2.2 to 2.4) must be indicated in German and in a clear and visible manner. This must be indicated both when offering the product (for example in the product description online) as well as on the product and/or on the product packaging.

Mandatory indications such as manufacturer identification must be affixed to the product by labelling or marking, such as a sewn-on label, or, when this is not possible (e.g. marking or affixing a label would inevitably damage the product), on its packaging. However, other aspects may also justify placing the required information on the packaging only. Such exemptions may arise for reasons of proportionality, for example because affixing a label or marking on the mask

- would be inappropriate for hygienic reasons (e.g. because microorganisms could more easily establish themselves or spread on these surfaces), or
- would compromise the product design or the function of the mask (e.g. wear comfort, fit, sealing or other central functions of the mask), or
- would be only possible at unreasonable costs (e.g. because of supply difficulties and other supply chain problems due the impact of the COVID-19 outbreak).

Textile Labelling: Textile products sold in the EU must comply with the European Textile Regulation. In general, they must carry a label or marking directly on the product clearly indicating the full fibre composition and, if applicable, the presence of non-textile parts of animal origin. However, the main purpose of the European Textile Regulation is to ensure that the consumer receives this information before purchase. This is achieved, in the vast majority of cases, by indicating the required information on the packaging of the textile product and, in the case of distance selling, additionally on the respective online product page or catalogue.

Warnings and instructions for the use of the mouth and nose masks (e.g. instructions how to correctly wear or care for the mask or other information the consumer needs in order to assess the risks and protect themselves against the risks) may be provided on the product **packaging or** on an **accompanying separate document (e.g. manual)** which either can be provided in paper form or sent in PDF format by email (e.g. together with the order or shipping confirmation).

In cases where the masks are also intended for countries other than Germany, manufacturers or importers are recommended to consider possible deviations on product (labelling) requirements based on national provisions (e.g. with regard to care or size labelling requirements).

2.6 Checklists:

⇒ *Make it clear that the mouth and nose mask is not a medical device or PPE (also do not give this impression)*
[see questions 2.2 and 2.4].

⇒ *Meet the product labelling requirements (in particular textile labelling, manufacturer and product identification labelling).*
Indicate the required information by affixing it to the textile product (labelling) or directly on the product (marking) and/or on its packaging. In case of distance selling, provide the information additionally on the respective online product page or catalogue.
[see questions 2.3 to 2.5].

⇒ *Indicate other required information, in particular warnings and instructions, on the product packaging and/or on an accompanying separate document (e.g. manual) and, in case of distance selling, additionally on the respective online product page or catalogue.*
[see questions 2.4 and 2.5].

3. Technical information and recommendations

When manufacturing mouth and nose masks (see question 2 above) it is recommended that the following requirements/suggestions are taken into account (see questions 3.1 and 3.2 below). This is not a binding or exhaustive list.

3.1 What general requirement profile should mouth and nose masks fulfil?

- Fit: Thin woven fabrics, knitted fabrics and non-wovens fit the head shape in the mouth and nose area well. A correspondingly optimised cutting pattern also supports a good fit of the mask. Furthermore, the mask should be constructed in a way that it can fit sufficiently tightly whilst being worn.

- The mask should be made of a dense woven fabric or a combination of woven and non-woven fabric to be able to achieve a certain filtering effect.

- Using multiple layers of the same or different textile raw materials (woven or knitted fabrics or non-wovens etc.) is advantageous. At the same time, it is necessary to ensure that sufficient breathability or air permeability is provided.

- Reusable mouth and nose masks should be boil-proof or at a minimum washable at 60 or 75 degrees Celsius (using suitable disinfectants, if necessary). The maximum number of wash cycles before the mask loses its water-repellent or other important functions should also be stated, if significant.

- It should be ensured that the mask does not get saturated with moisture too quickly. Moisture increases the risk that (possibly infectious) droplets may pass through the mask.

3.2 What should be considered when choosing materials and their impregnation/finishing?

- Woven fabrics should have as high a thread count as possible. Knitted and non-woven fabrics should have a correspondingly high density.

- Non-wovens made of polypropylene, polyester or polyethylene are particularly well suited due to their filtering effect and construction, as they absorb low levels of moisture. They are therefore well suited for the middle layer of multi-layered masks.

- Woven or knitted fabrics made of synthetic fibres (polyester, polyamide etc.) are good at relaying moisture. In comparison, fabric made from cotton or viscose fibres easily absorbs moisture. This aspect should be adequately taken into account and, in particular, a water repellent (hydrophobic) finish should be considered. In addition fibres with a low particle shed rate are preferred.

- Water repellent finishing is optimal as this is suitable for more wash cycles at higher temperatures. In the area of personal protective equipment, for example, fluorocarbon finishing is an established method. The water repellent impregnation is reactivated after ironing the washed masks.

- Alternative water-repellent products, such as silicone or wax based, are less suitable as they have less washing resistance at higher temperatures. They are, however, better than having no water-repellent finishing at all.

- If biocidal products are used the relevant legal requirements must be observed.

- Straps made of textile fabric are recommended to attach the mask to the head. Commercial elastic straps (with a few exceptions) usually do not have sufficient washing resistance at high temperatures.