IFA
Institut für Arbeitsschutz der
Deutschen Gesetzlichen Unfallversicherung

# FAQ: Check for suitable FFP2 masks

**1. Where can I find tips on how to recognize whether a mask is "safe" (tested)?**

We have issued a poster. It provides information on the most important characteristics that a properly approved particle filtering face piece (FFP) must possess. Should any of these characteristics be absent from the mask, caution is advised.

The characteristics at a glance:

**Legally required information, which must be declared on the product:**

- CE marking, always followed by the 4-digit code of the notified body responsible for surveillance
- Protection class FFP1, FFP2 or FFP3, followed by a mandatory suffix (NR = not reusable after one shift – or - R = reusable); where applicable, with the optional D suffix for high dust levels
- Number and year of publication of the European standard EN 149
- Manufacturer's name/identity and product name

**Documents to be supplied with the product as a legal requirement:**

- Instructions for use (information brochure) in the language of the country in which the product is distributed (in German for the German market)
- Manufacturer's declaration of conformity (either in the instructions for use, or available on the Internet via a link provided in the instructions for use)
- EU type-examination certificate for the mask. The certificate is not normally supplied together with the product

**2. Can I check whether the notified body stated on the mask (CE XXXX = four-digit code identifying the notified body responsible for surveillance) actually exists?**

The EU Commission's NANDO database lists the "notified bodies" in Europe. For respiratory protective devices, the search under "Products" must be narrowed to "Equipment providing respiratory system protection" and under "Procedure" to "Supervised product checks at random intervals /Annex VII". These search criteria return an up-to-date list of European notified bodies responsible for the surveillance of respiratory protective devices.

The database is available in English only.

### 3. When is a mask defective?

The issue of defective or fake respiratory masks is limited for the most part to particle-filtering half masks, which are intended to provide reliable protection for the wearer against exposure to hazardous substances or pathogens. These masks therefore constitute personal protective equipment (PPE).

FFP masks are subject to mandatory testing of their compliance with the requirements of the EU PPE Regulation before they may be placed on the European market. European standard EN 149, Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking (EN 149:2001+A1:2009), is applied for this purpose. Where the product's performance has not been tested against the test standard by an independent testing body, certification is not possible and the manufacturer may not apply CE marking to his product. Should such a mask nevertheless be advertised and marketed as an FFP mask, it must be assumed that the requirements for its performance are not met, that the mask therefore does not provide reliable protection, and that it must consequently be classified as defective.

### 4. How many defective masks are currently on the market?

Just how many fake or defective products are currently on the market is not known. The situation is very complex, since a fake certificate does not necessarily mean that the products themselves are defective, or vice-versa. Even an expert cannot determine with absolute certainty whether a product is fake without testing it in the laboratory. Furthermore, other products enjoy official approval for the purposes of protecting against infection during the pandemic. Details of these products can be found in the overview of personal protective equipment (PPE) for SARS-Cov-2 provided on our website (available in German only). Where fake IFA certificates have been discovered, for example, it was shown that in some cases the dealers concerned were inexperienced and naive. Professional manufacturers of certified PPE have been familiar with the rules for many years.

### 5. Are other products available that offer the same protection against SARS-Cov-2 as FFP2 masks?

Where a KN95 mask complies with the Chinese GB 2626 standard, it may be assumed to offer a comparably high level of protection against infectious agents. Such masks are however not approved for the European Single Market without further testing and special measures on the part of the authorities. Between March and the end of September 2020, a special procedure was in place by which CPA masks – predominantly KN95 masks – underwent a rapid test and were placed on the market by way of special regulatory approval for their use for the purpose of protection against infection. These masks were still accepted and approved with any marking (including symbols such as "FFP2" or "CE") up until the beginning of June 2020. This is particularly confusing for lay persons. The equivalence of these CPA masks to FFP2 masks has however not been explicitly demonstrated by the rapid test. These products may nevertheless also be assumed to offer protection against infectious agents. Provided they are not equipped with a valve, they are also suitable for use in the medical field. These masks are however also frequently placed on the market in inferior quality and/or with a false declaration (such as the false claim that they are certified FFP2 masks).

**6. Where do I find the EU type-examination certificate for the mask?**

The manufacturer must be able to produce a valid certificate – the EU type-examination certificate – upon request. This certificate is issued by an independent body. Some notified bodies have published information in a database on the certificates that they have issued. Valid certificates issued by the IFA can be searched for in the certificate database of DGUV Test, provided the manufacturer has consented to this information being published there.

**7. Can I determine whether the EU type-examination certificate for the mask is genuine?**

Only the issuing bodies themselves can provide absolute certainty. The EU Commission's in turn provides a good indication of whether the testing body stated on the certificate actually exists and is authorized to conduct certification of respiratory protective devices NANDO database (see question 2). In this case, the search must be narrowed under "Procedure" to "EU type-examination/Annex V" and under "Products" to "Equipment providing respiratory system protection". These search criteria always return the up-to-date list of European notified bodies for type examination of respiratory protection products. This method can be used to determine quickly whether further checking is worthwhile.

The certificate must:

- be issued by a notified body within the EU
- bear the heading "EC type-examination certificate"

Images of the manufacturer's certificates can often be found on the website of the manufacturer named on the certificate. Should doubts exist as to whether the scan or copy of a certificate is genuine, a comparison may be informative.

Information and guidance on frequently forged certificates can also be found on the following websites:

- Safety Gate: the European Commission's rapid alert system for dangerous non-food products. On the search form, select the term "Protective equipment" in the "Category" field.
- COVID-19 pages of the European Safety Federation
- Thomas Vierhaus: Article on sifa-sibe.de concerning unusable certificates (4.2020) (German website only)

**8. Where can I find the manufacturer's declaration of conformity for the mask when it is not supplied with the product?**

The manufacturer's declaration of conformity is often included within the instructions for use. If this is not the case, it must be referred to by a link. If neither is the case, caution is advised.

**9. Can I determine whether the manufacturer's declaration of conformity for the mask is genuine?**

Since November 2020, it has been possible to check declarations of conformity of medical devices and protective equipment for plausibility by uploading them to the website of the VDE (German Association for Electrical, Electronic & Information Technologies) (German website only).

**10. In Germany, must the mask be accompanied by instructions for use in German?**

The manufacturer of a certified mask must provide instructions for use in in the language of the country in which the product is distributed (in German for the German market). Instructions for use must be supplied with each smallest commercial packaging unit. A package containing ten masks thus contains only one copy of the instructions for use. However, the instructions for use can also be made available on the manufacturer's website. If no instructions for use whatsoever are available, caution is advised.

**11. Is an FFP2 mask with a valve always a fake?**

No. FFP2 masks are manufactured both with and without a valve. The requirements of European standard EN 149:2001+A1:2009 apply to both variants. Proof of performance as described above must be provided in both cases. On a mask equipped with a valve, only the inhaled air is filtered; the mask provides no external protection, i.e. to other persons. Any exhaled pathogens pass through the valve into the surrounding air.

**12. Do other masks exist with which I can protect myself?**

Persons seeking to protect themselves against infectious agents can do so not only by means of a particle-filtering half mask of protection class FFP2 or FFP3, but also by means of a half or full-face mask of rubber or silicone with one or, in the case of double-filter masks, two matching replaceable class P2 or P3 particle filters. FFP3 masks or half or full-face masks with P3 filter are used for particular occupational hazards.

**13. Where can I purchase an approved FFP2 mask?**

- From a technical trade dealer in PPE. Technical trade dealers often sell only to commercial purchasers and not to private end customers.

- DIY stores and pharmacies, where these outlets can provide credible assurance that professional discernment has been applied in sourcing (see Check 5 on the poster for checks for the suitability of respiratory masks).