

Face-masks: Product labelling and certificates Questions & answers for business customers, manufacturers and distributors

I. QUESTIONS ABOUT MASKS

1. What is a mouth-nose protection (MNP) and what is its field of application?

What is a MNP?

ANSWER

- Mouth-to-nose protection (MNP) is usually referred to as "mouth-nose-masks" or "community masks".
- In private use, the MNP serves as a mechanical barrier and is intended to protect the environment from droplets produced by talking, sneezing, and coughing in the context of mindful interaction with other people.

There are no special legal requirements for the MNP.

- However, for this area, OETI offers community mask testing and the product labelling "INSPECTED QUALITY for MOUTH-NOSE-MASKS", which is based on the specifications of the workshop agreement CWA 17553. The agreement was created by an independent organisation (= by CEN members* (European Committee for Standardisation)).

Consequently, OETI provides you, your business partners, and consumers with a reliable label, that is based on the specifications of an independent, external body.

- MNP is not PPE (personal protective equipment), therefore OETI does not issue PPE certification for this type of mask.
- MNP is also not a medical mask, so no certification is possible for this either.
- For manufacturers / distributors of community masks our OETI experts are at your disposal for any questions regarding community mask testing and the product labelling "INSPECTED QUALITY for MOUTH-NOSE-MASKS".

Please contact us by e-mail at oekologie@oeti.biz.

Where are "MNP" used?

ANSWER

- These masks can be used wherever the wearing of masks is required but where no special requirements (e.g. FFP2) apply.



2. What is an FFP respiratory protection mask and its area of application?

What is an FFP-mask?

ANSWER

- These are particle-filtering half masks which are divided into three classes (FFP1 / FFP2 / FFP3) according to the filtering performance achieved.

FFP masks usually consist entirely of the filter medium and can be equipped with an exhalation valve.

- These masks are personal protective equipment (PPE).

The OETI certification body issues a PPE certification (EU type examination) for this type of mask.

Since the beginning of April 2020, OETI has been approved as the first certification body in Austria for the EU type examination (CE marking) of FFP masks.

- If you are a manufacturer / distributor of masks OETI's experts are at your disposal for any questions regarding the certification of FFP masks as well as giving you a quotation for your mask certification.



Where are FFP masks used?

ANSWER

- These masks protect the wearer against particles (e.g. dust, viruses, ...). Masks without an exhalation valve also protect the people around you.

For the use of these masks, the current Covid-19 legal requirements in your home country must be observed!

- **For a quote, please contact us by email at ppe@oeti.biz.**

3. What is a KN95-mask?

ANSWER

- This is a mask which has been tested according to a Chinese standard (GB2626-2006).

4. What is a CPA-mask and its area of application?

ANSWER

- These are "Corona SARS-Cov-2 Pandemic Respirators (CPA)".

At the beginning of the pandemic, a legal basis was created to enable respiratory masks for the exclusive use of medical professionals to be assessed more quickly. Based on the Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat the Austrian government issued a decree (enactment 2020-0.198.830 (dated 02 April 2020)).



This shortened procedure enabled masks without CE marking to be placed on the Austrian market.

ATTENTION: This Austrian decree has expired at the end of 31 March.

Please note that the implementation of the Commission Recommendation (EU) 2020/403 of 13 March 2020 was legally different transposed by individual EU member states. Thus, different legal regulations and deadlines apply in the individual member states.

5. Surgical / medical mouthguard and its field of application?

What is a surgical / medical mouthguard?

ANSWER

- This is a medical device that covers the mouth and nose and provides a barrier to minimise the direct transmission of infectious germs between medical staff and patients.
- This type of mask does not count as personal protective equipment (PPE). OETI does not issue PPE certification for this type of mask.

Where are surgical / medical mouthguards used?

ANSWER

- The main intended use of medical face masks is to protect the patient against infectious germs and, additionally in certain situations, to protect the wearer against splashes of possibly contaminated liquids.
- OETI is not a certification body for medical devices and therefore not for surgical / medical mouthguards.

II. QUESTIONS ON THE PERIOD OF VALIDITY OF CERTIFICATES

1. Questions about certificates (FFP): How long are the certificates for FFP valid?

ANSWER

- The period of validity is indicated on the respective certificate.
- **For questions regarding certificates of FFP masks and/or for a quotation, please contact us by e-mail at ppe@oeti.biz.**

Please note that we cannot answer questions about certificates that were not issued by OETI (in these cases, please contact the certification body that issued the respective document).

2. Questions about certificates (CPA): How long are the certificates for CPA valid?

ANSWER

- The period of validity is limited to the current COVID 19 crises.



- **ATTENTION: This Austrian decree for CPA masks has expired at the end of 31 March.**

Please note that the implementation of the Commission Recommendation (EU) 2020/403 of 13 March 2020 was legally different transposed by individual EU member states. Thus, different legal regulations and deadlines will apply in the individual member states.

Please note that we cannot answer questions about certificates that were not issued by OETI (in these cases, please contact the certification body that issued the respective document).

3. Questions about certificates (MNP): There is no certificate, but the product label "INSPECTED QUALITY for MOUTH-NOSE-MASKS".

ANSWER

- There are no special legal requirements for the MNP. However, for this area, OETI offers community mask testing and the product labelling "INSPECTED QUALITY for MOUTH-NOSE-MASKS", which is based on the specifications of the independent workshop agreement CWA 17553.
- The label is valid for one year.
- If you are a manufacturer / distributors of community masks our OETI experts are at your disposal for any questions and/or a quote.
- **Please contact us by e-mail at oeekologie@oeti.biz.**

4. Questions about certificates (surgical / medical masks): How long are the certificates valid?

ANSWER

- OETI is NOT a certification body for medical devices and therefore not for surgical/medical mouthguards. Please note that we cannot answer questions about certificates that were not issued by OETI.

III. PLACING OF MASKS ON THE MARKET

5. What must be done to place FFP masks on the market?

ANSWER

- This requires the carrying out of a conformity assessment procedure according to Regulation (EU) 2016/425 and the complete performance of all tests according to EN 149.
- If you are a manufacturer / distributor of masks and would like to have your masks certified, the OETI experts are at your disposal.
The OETI is the first approved certification body for FFP masks in Austria.



- Please contact us by e-mail at ppe@oeti.biz.

6. What must be done to place medical masks on the market?

ANSWER

- OETI is not a certification body for medical devices and therefore not for surgical / medical mouthguards. Please note that we cannot answer any questions about certificates that were not issued by OETI.

IV. FURTHER QUESTIONS

1. How can I tell which type of mask it is?

ANSWER

- The labelling of the mask provides information about this:
 - MNP masks are usually not labelled in Austria unless they are tested by OETI according to "INSPECTED QUALITY for MOUTH-NOSE-MASKS".
 - Surgical / medical mouthguards are designated as such on the packaging. The standard number EN 14683 may also be indicated.
 - FFP-masks:
 - Is referred to as FFP-masks (e.g. FFP2)
 - Are tagged as EN 149:2001+A1:2009
 - Carry the CE mark
 - Have a four-digit number to identify the certifying body

2. My mask has a certificate. How can I check whether the certificate is valid?

ANSWER

- If you have any questions about certificates issued by OETI, please contact us by email at ppe@oeti.biz.
- Please note that we cannot answer questions about certificates that were not issued by OETI (in these cases, please contact the certification body that issued the respective document).

3. My FFP mask is CE marked - is this valid and really certified?

ANSWER

- They must be referred to as FFP mask (e.g. FFP2) on the packaging and the mask itself.
- The number of the test standard (EN 149:2001+A1:2009 plus class e.g. FFP2) must be stated on the packaging and the mask itself.
- The CE mark must be shown on the packaging and the mask itself.



- The four-digit number identifying the certifying body must be stated on the packaging and the mask itself.
- The user information, which provides information on the handling of the mask, must be available.
- The EU declaration of conformity or a reference (link) where the EU declaration of conformity can be retrieved must be shown on the packaging.

4. Is it sufficient if the website of the mask manufacturer / distributor states that the masks are CE certified?

ANSWER

- No, the masks must also be correctly labelled according to European law (see previous answer).

5. Is a CPA mask equivalent to a FFP mask?

ANSWER

- Due to the different testing and approval procedures for FFP masks and CPA masks, the results are not comparable.

6. Which mask is better: CPA vs. FFP?

ANSWER

- Due to the different testing and approval procedures for FFP masks and CPA masks, the results are not comparable.

7. Can I clean my FFP mask again?

ANSWER

Cleaning of the FFP masks is only permitted if this cleaning is described by the manufacturer and has been checked during the certification process.

Information on whether and how cleaning is possible is provided in the user information enclosed with each FFP mask.