Face masks: not just anything will do

The need for face masks during this COVID-19 pandemic is enormous. People are encouraged to sew, 3D print, even crochet and knit face masks, from the - understandable - idea that you are better protected a little bit than not at all.

Yet we want to make sure that our medical professionals are adequately protected and don't get a false sense of security, which can put them and the general public health at great risk.

That's why, as a certified laboratory authorized to test medical face masks, we are happy to provide information on the performance requirements for a safe medical face mask according to the European Medical Device Directive.

Contents

Technologiepark 70 – BE 9052 Zwijnaarde
Rue du Travail 5 – BE 4460 Grâce-Hollogne
https://www.centexbel.be

What does a face mask protect against?

When breathing, speaking, coughing, sneezing, etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose. The majority of the nuclei are between 0,5 µm and 12 µm in diameter and especially the larger droplets can contain microorganisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.

Face masks cover the wearer's mouth and nose and protect healthcare professionals and patients' visitors from infections and come in different shapes and sizes. For optimal protection, you need to know which face mask is suitable for what. European directives and standards have been drawn up for this purpose.

You can only be sure that a face mask offers the necessary protection if it complies with these European standards. It is therefore not possible to make a mask that offers sufficient protection from any which material.

Face masks are only effective if the generally applicable hygiene regulations are observed.

Technologiepark 70 – BE 9052 Zwijnaarde
Rue du Travail 5 – BE 4460 Grâce-Hollogne
https://www.centexbel.be

Types of protective face masks and their use

Medical face masks

Your Centexbel contact:

Mark Croes – mc@centexbel.be

A medical face mask is worn by doctors and medical staff and is a medical device that protects the patient against pathogens from the nose or mouth of hospital staff. In addition, it protects medical staff members from touching their own mouth or nose with their hands or gloves.

These face masks are used by healthcare providers to protect the patient from exposure to microorganisms released during talking, coughing and sneezing by the healthcare provider. Thus, the filtering capacity of surgical oral masks works from the inside out and can vary greatly (from 0.5 microns to 5 microns or more).

Medical face masks must comply with the **Medical Devices Directive** and the European standard **EN 14683**. The use of a suitable mask is an effective means of protecting the work environment from drip contamination from the nose and throat during health care procedures. However, masks with very different performances are available. Therefore, factors such as the risk of infection and the fit of the mask should be carefully considered when choosing a mask.

Although surgical masks are not respiratory masks, they can provide protection when infectious microorganisms are being manipulated. They form a physical barrier to nasal and oral mucous membranes, preventing the transmission of microorganisms through droplets or splashes of infected material.

There are 3 types of medical face masks:

- **Type I**: to be worn by patients, not medical staff.
- **Type II**: to be worn by medical staff in those cases when a medical face mask is required, but where there is no risk of splashes of body fluids.
- **Type IIR**: this moisture impermeable variant is intended to protect the nasal and oral mucous membranes against splashes of body fluids.

The following information shall appear on the product or packaging:

- Number of the European standard followed by the year of publication of the standard. E.g. EN 14683:2019 (latest publication)
- Type of mask
- CE marking

If you want to offer these products as sterile you will have to involve a Notified Body. Of course, this will impact production, packaging, markings and more.

- STERILE must be added to the Type information.
- CE marking will be followed with the four-digit ID of the Notified Body involved in type testing the product and auditing the production.
- Manufacturer must be certified to EN ISO 13485

Sterile or not, ALL medical devices need to be registered with the national authorities! Each EU Member State has its own database. If these statements are not present, it is not certain that the medical face masks are in conformity with the standard. It is then possible that they do not offer (the needed) protection.

CENTEXBEL
Technologiepark 70 – BE 9052 Zwijnaarde
Rue du Travail 5 – BE 4460 Grâce-Hollogne
https://www.centexbel.be

COVID-19 advice for healthcare providers

Use medical face masks of Type IIR.

Respiratory protection masks

Your Centexbel contact:

Inge De Witte – idw@centexbel.be

A respiratory protection mask is used to protect the wearer from inhalation of all kinds of solid particles - also outside the medical context - and must comply with the **European Personal Protective Equipment Directive** and the European standard **EN 149:2001+A1:2009** - *Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking*.

FFP2 masks, which are currently often mentioned in coronavirus reports, are used in hospitals by doctors and nurses who come into contact with infected patients and meet very strict requirements as described in EN 149:2001.

Technologiepark 70 – BE 9052 Zwijnaarde
Rue du Travail 5 – BE 4460 Grâce-Hollogne
https://www.centexbel.be

However, these masks are not tested for e.g. Bacterial filtration efficiency (BFE) and Microbial cleanliness (Bioburden). They are intended to protect the wearer from inhaling small particles. The gradation depends largely on the degree to which the filter (the material of which the mask is made) retains the particles and how well the mask seals. There are filters that retain dust (indicated by the letter P), filters that absorb gases/vapours (indicated by the letter A) and filters that can retain both dust and gases/vapours, the so-called combination filters.

For respiratory protection against infectious aerosols* dust filters can be used. However, it should be noted **that these dust filters do not protect against gases or vapours**. Based on the filter penetration, they are divided into three classes: P1, P2 and P3.

There are 3 types of respiratory protection masks:

- **FFP1 mask**:** this is the lowest level of performance a protective mask can offer. This mask has an efficiency of at least 80% against airborne particles. The side leakage (around the face) must not exceed 22%. This mask is used when the norovirus is present.
- **FFP2 mask:** Is the average category of protective masks and has an efficiency of 94% solid and liquid irritant aerosols. The side leakage should not exceed 8%. This mask is used when TBC is present.
- **FFP3 mask:** This class provides high protection against solid and liquid toxic aerosols and has a minimum efficiency of 99%. The side leakage must not exceed 2%. This mask is used when working with cytostatics.

Please note:
* FFP means Filtering Face Piece
** An aerosol is a colloidal mixture of dust particles or liquid droplets in a gas.

In addition to the penetration levels (see table below), respiratory protective masks must meet a range of other requirements.

Table 1 — Penetration of filter material

Classification	[A1] Maximum penetration of test aerosol [A1]	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

The following indications are present on the product:

- The standard with which the product complies + the year of publication of the standard; e.g. EN 149:2001+A1:2009 (last publication date)
- The class to which the product conforms (FFP1, FFP2 or FFP3)
- CE marking and notified body number

If these statements are not present, it is not certain that the masks are in conformity with the standard. It is then possible that they do not offer (the needed) protection.

COVID-19 advice for healthcare providers

In the case of a disposable respiratory protection mask, use a type without an exhalation valve, as there is a risk of droplets entering through the valve in the event of a splash.

Questions and Aswers

Q: What type of mask is recommended?

A: The hospital decides which type of mask to use on the basis of a risk analysis. In order to avoid errors between type I and type II, only one type is often used in institutions: Type IIR.

Q: Should face masks be sterilized?

A: In principle, it is not necessary for the masks to be sterilized provided that they have been produced under the correct hygienic conditions. The masks are therefore tested for this parameter.

Q: When do you put on a new face mask?

A: The risk of contamination due to hand contact with a used mask means that it is essential that the mask is taken off and discarded if it is no longer worn over the nose and mouth. If further protection is needed, a new mask shall be put on. Touching a used face mask or putting on a new face mask shall always be followed by a full hand disinfection procedure and a used mask shall always be discarded when it is no longer needed or in-between procedures.

Due to the fact that used masks are considered to be highly contaminated, the following recommendations are essential:

- *the mask is not touched by the wearer's fingers/hands;*
- *the hands are disinfected (complete hand disinfection) after removing the mask;*
- *a mask is worn covering the wearer's nose and mouth, at no time does a mask hang around the wearer's neck;*
- *a used mask must be discarded when it is no longer needed or in-between procedures; if there is a further need for protection, a new mask shall be put on.*

Q: What tests are medical face masks subjected to and how can I be sure that the mask I purchase meets the requirements?

A: Medical oral masks are subjected to five tests described in EN 14683. All tests are performed on the mask as a finished product or on samples cut from masks as finished products.

More information at https://www.centexbel.be/en/testing/evaluation-medical-face-masks

- *Bacterial filtration efficiency (BFE)*

- *Breathability*
- *Splash resistance*
- *Microbial cleanliness (Bioburden)*
- *Biocompatibility*

Table 1 — Performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

Source: All information on the testing of medical face masks is published in EN 14683:2019.

You can order this standard via NBN in Belgium – https://www.nbn.be/[1]

Q: What if healthcare providers do not have medical face masks to protect themselves against COVID-19?

If you do not have a certified medical face mask while performing medical care tasks, at least use a disposable respiratory protective mask without an exhalation valve, as there is a risk of droplets entering through the valve in the event of a splash.

[1] https://www.nbn.be/nl/nieuwsberichten/gratis-normen-voor-mondmaskers
NBN puts the standards on face masks and personal protective equipment at the free disposal of Belgian stakeholders on a temporary basis.