HOHENSTEIN

# Medical face masks – Requirements and test methods

The main intended use of medical face masks is to protect the patient from infective agents and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids.
Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

## This test is particularly suitable for

- Medical face masks / surgical face masks

## Customer benefit

Surgical masks are considered medical devices class I in Europe and are covered by Medical Device Regulation 2017/745. With our tests, we accompany your preparation of technical documentation and clinical evaluation for approval as a medical product.
Please be aware that for complete approval as a medical product, further tests and documents are needed.

*Because of the Corona crisis the requirements for each country might be different than normal.*

# Description

Specified in the European Standard EN 14683, medical face masks are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.

## ASTM Level 1 (EN 14683 Type I / Type II)

**Bacterial Filtration efficacy EN 14683 Annex B**

- A sample of the mask material is clamped between an aerosol chamber and a six-stage cascade impact device. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn under vacuum through the mask material and the impact device. The bacterial filtration capacity of the mask is defined by the number of colony forming units passing through the mask.

**Differential pressure EN 14683 Annex C**

- In a test setup, the pressure difference is measured by drawing air through a defined base area of the material at an air flow of 8 l/min. The test is an indicator for the breathability of the face mask.

**Microbial cleanliness (Bioburden) ISO 11737-1**

- The test evaluates the total germ count of the sample material in fulfilment of the microbiological requirements for medical devices.

## ASTM Level 2 (EN 14683 Type IIR) in addition to Level 1

**Resistance to penetration by synthetic blood ISO 22609**

- A defined volume of synthetic blood is shot from a pneumatically controlled valve onto the sample at defined velocities to simulate the spraying of blood and other body fluids onto the sample material. The back of the mask is visually inspected and swabbed for fluid leakage.

## Biocompatibility test for medical devices

**Cytotoxicity ISO 10993-5**

- In the cell culture test, skin cells are used to detect cell-damaging substances (cytotoxins) that can be released from the sample material. The test thus allows the assessment of a potential risk of cell damage for products worn close to the skin.

# Test sample requirements

### Quantity of material

- Type I / Type II: A total sample quantity of 50 specimens is required.
- Type IIR: A total sample quantity of 130 specimens is required.

### Test duration

- Lead time for full testing is approx. 3 weeks.
- Individual results can be made available earlier:
  EN 14683 Annex C and ISO 10993-5 – approx. 1 week
  EN 14683 Annex B and ISO 11737-1 – approx. 2 weeks
  ISO 22609 – approx. 3 weeks

### Requirements for ISO 11737-1 (Bioburden)

- Mask samples for testing should be provided in the original primary packaging (dispenser box or equivalent) as offered to the end user.
  If the mask contains a visor or other accessories it should be included in the testing.

# Differences between medical face masks and respiratory protection*

### Medical face masks

A medical or surgical face mask primarily reduces the (potentially infectious) saliva/mucus droplets of the wearer's mouth/nose entering the environment. Since the mask does not fit tightly, it does not provide sufficient protection against airborne infections. However, the wearer's mouth and nose can be protected by the mask against contact with contaminated hands. Medical face masks must comply with EN 14683 "Medical face masks - Requirements and test methods“.
A face mask is no respiratory protection!

### Respiratory protection

Particle filtering face pieces (FFP) protect against solid or liquid aerosols. As classical personal protective equipment, they are subject to Regulation (EU) 2016/425 for PPE. Particle filtering half masks must meet the requirements of DIN EN 149 "Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking". The standard differentiates between the device classes FFP1, FFP2 and FFP3 depending on the retention capacity of the particle filter. A tight-fitting FFP2 mask provides suitable protection against infectious aerosols, including viruses. Wearing an FFP half mask for long periods of time can be physically demanding.


* Source: BAuA (Federal Institute for Occupational Safety and Health)