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# Minimale eisen en testprocedures voor maskers voor gebruik bij de COVID-19 virus pandemie (EN 14683:2019+AC:2019)

# Contents

# Introduction

This document describes the minimal requirements and test procedures for medical face masks which are intended to be used during the corona SARS-CoV-2 virus pandemic. These requirements and procedures are based upon recommendations of the EU Commission (2020/403) of 13 March 2020.

## Reference list

- EN 14683:2019+AC:2019 (gratis verkrijgbaar via https://www.nen.nl/NEN-Shop/Nieuws-Medische-hulpmiddelen/Normen-voor-persoonlijke-beschermingsmiddelen-en-medische-hulpmiddelen.htm)
- EN ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
- EN ISO 11737-1:2018, Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
- ISO 22609:2004, Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
- Hohenstein
- Nelson lab
- Centexbel
- Aitex

# General Overview of the tests to comply with EN14683

## Materials and construction

The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or molded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.

## Design

The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.
Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).

# Tests

1. Bacterial filtration efficiency
2. Differential pressure
3. Splash resistance pressure
4. Microbial cleanliness

In table 1 you will find the performance requirements, i.e. criteria to pass for the tests.

| Test | Type I * (patiënts) | Type II (professionals) | Type IIR (professionals) |
|---|---|---|---|
| **Bacterial filtration efficiency (BFE), (%)** | ≥ 95 | ≥ 98 | ≥ 98 |
| **Determination of breathability (differential pressure), (Pa/cm2)** | < 40 | < 40 | < 60 |
| **Splash resistance pressure, (kPa)** | Not required | Not required | ≥ 16,0 |
| **Microbial cleanliness (Bioburden), (cfu/g)** | ≤ 30 | ≤ 30 | ≤ 30 |

Table 1 — Performance requirements for medical face masks

** 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.*

A minimum of 50 masks is needed cover the tests Bacterial filtration efficiency, Determination of breathability, Microbial cleanliness, Citoxicity and when covering biological evaluation by a rationale. When including also an irritation test you can reach up to 85 masks. Mind that some labs require additional spares, and these are variable amounts. To reduce the number of masks needed, for some tests material fragments of 10cmx10cm can be tested instead of the mask.

# Test Bacterial filtration efficiency (BFE)

Tested accordingly Annex B minimum value per type see also table 1.
Source: EN 14683; ANNEX B

**When a mask consists of two or more areas with different characteristics or different layer composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.**

## Principle

A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

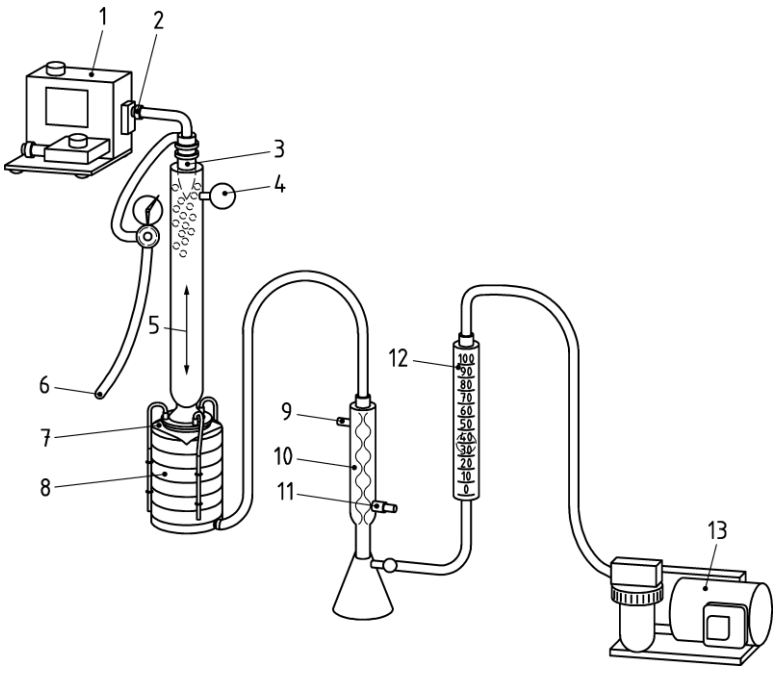


Figure B.3 — Example of real BFE test apparatus

1 drive mechanism 8 cascade impactor
2 bacterial suspension 9 outlet to sink
3 nebulizer 10 condenser
4 filter 11 cold water inlet
5 aerosol chamber 12 calibrated flow meter
6 high pressure air source 13 compressor (vacuum pump)
7 test material

## Test specimen

- Number of specimen: at least 5
- Test complete mask (remove the extremities) or take a specimen of at least 100 mm x 100 mm from the complete mask to secure it can be laid down flat.

## Test conditions

- Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h to bring them into equilibrium with atmosphere prior to testing.

## Test criteria

| Test | Type I a (patiënts) | Type II (professionals) | Type IIR (professionals) |
|---|---|---|---|
| **Bacterial filtration efficiency (BFE), (%)** | ≥ 95 | ≥ 98 | ≥ 98 |

# Test Determination of breathability (differential pressure)

The breathability is represented by the differential pressure required to draw air through the mask. Testing is performed according to EN14683, Annex C table 1

## Principle

A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure C.1. A water-filled (or digital) differential manometer is used to measure the differential pressure. A mass flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the test apparatus and a needle valve is used to adjust the airflow rate.

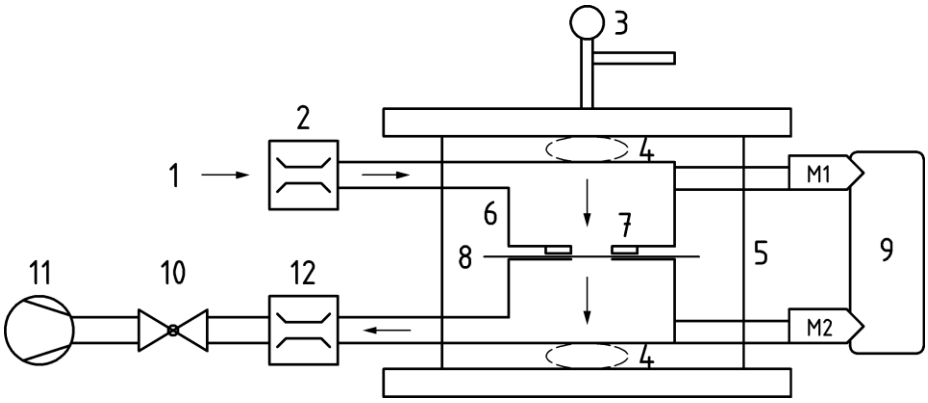


Figure C.1 — Test apparatus for measuring differential pressure

## Test specimens

- 5 test specimen must be taken/cut from complete masks each with a surface of a diameter of 25mm.
- Unless otherwise specified, the testing shall be performed with the airflow direction from the inside of the mask to the outside of the mask.

## Test conditions

- Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h.

**Test criteria**

| Test | Type I a (patiënts) | Type II (professionals) | Type IIR (professionals) |
|---|---|---|---|
| **Differential pressure (Pa/cm2)** | < 40 | < 40 | < 60 |

# Test Splash resistance pressure

**ISO 22609;2004** See also table 1 of EN 14683 Performance requirements for medical face masks (Type IIR)

## Principle

A specimen medical face mask is supported on an apparatus. A volume of synthetic blood is sprayed horizontally at the specimen mask to simulate the scenario of a mask being splashed by a punctured blood vessel. The volume of fluid, distance to impact, orifice size and fluid velocity are defined in this method and intended to be consistent with this health care scenario.

Specimen medical face masks are evaluated at a total of three different velocities ( 450, 550, 635 cm/s) corresponding to human blood pressures of 10,6 kPa (80 mmHg), 16,0 kPa (120 mmHg), and 21,3 kPa (160 mmHg) (see table 1).

Test results are reported at each velocity and the medical face mask is rated at the highest corresponding blood pressure for which medical face mask specimens demonstrate an acceptable quality limit of 4,0.

**Table 1 — Valve times for standard test pressures**

| Pressure (kPa) | Velocity (cm/s) | Valve time for standard apparatus and fluid (s) |
|---|---|---|
| 10,6 | 450 | 0,80 |
| 16,0 | 550 | 0,66 |
| 21,3 | 635 | 0,57 |

## Test Specimen

- 32 samples taken at random

## Test Condition

- Condition each specimen for a minimum of 4 h by exposure to a temperature of (21+5) °C and a relative humidity of (85 + 5) % using a controlled temperature and humidity chamber or space.

## Test criteria:

Any evidence of synthetic blood penetration on the side of the medical face mask contacting the wearer's face constitutes failure. Results are reported as "pass/fail". Van de 32 specimen 29 must pass. (Quality limit AQL 4%)
For type IIr masks, the splash resistance should be 16 Kpa (120 mmHg) at minimum.

| Test | Type I a (patiënts) | Type II (professionals) | Type IIR (professionals) |
|---|---|---|---|
| **Splash resistance pressure (kPa)** | Not required | Not required | ≥ 16,0 |

# Test Microbial cleanliness (Bioburden)

## Principle

An extraction is taken from the mask. This extraction is tested on microbial cleanliness. The bioburden is expressed in the number of colony forming units per gram extraction.

## Test specimen

5 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.

## Test criterium

When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1).

| **Test** | **Type I a (patiënts)** | **Type II (professionals)** | **Type IIR (professionals)** |
|---|---|---|---|
| **Microbial cleanliness (cfu/g)** | ≤ 30 | ≤ 30 | ≤ 30 |

Determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D of EN 14683.

Other test conditions as described in EN ISO 11737-1:2018 may be applied.
In the test report indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.

## Test Biocompatibility

For the biocompatibility of the medical face masks the manufacturer has to take into account:

1) Materials
   *It is recommended to use materials with a material ISO 10993 certificate.*
2) Manufacturing
   *Make a risk analysis on the contamination of the material in the manufacturing process per manufacturing step form the moment the raw material enters your manufacturing facility until the end product is packed for distribution.*
3) Packing
   *Use packing materials according with an ISO10993 certificate for the packing that is in contact with the product.*

According the ISO10993 the below listed aspects should be addressed:

- Cytotoxicity
- Sentization
- Irritation of intracutaneous reactivity

Sentization and Irritation of intracutaneous reactivity of the material are covered when the raw material is certificated under ISO10993.

Cytotoxicity must be tested in all cases.

Contact your test lab to get info on the amount and status of the test samples.