



**NSAI**  
Standards

Irish Standard  
I.S. EN 14683:2019

# Medical face masks - Requirements and test methods

**I.S. EN 14683:2019**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

*This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):*

*NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.*

*This document is based on:*

EN 14683:2019

*Published:*

2019-03-27

*This document was published under the authority of the NSAI and comes into effect on:*

2019-04-14

ICS number:

11.140

NOTE: If blank see CEN/CENELEC cover page

NSAI  
1 Swift Square,  
Northwood, Santry  
Dublin 9

T +353 1 807 3800  
F +353 1 807 3838  
E standards@nsai.ie  
W NSAI.ie

Sales:  
T +353 1 857 6730  
F +353 1 857 6729  
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

## National Foreword

I.S. EN 14683:2019 is the adopted Irish version of the European Document EN 14683:2019, Medical face masks - Requirements and test methods

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

**Compliance with this document does not of itself confer immunity from legal obligations.**

*In line with international standards practice the decimal point is shown as a comma (,) throughout this document.*

This page is intentionally left blank

EUROPEAN STANDARD

EN 14683

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2019

ICS 11.140

Supersedes EN 14683:2014

English Version

## Medical face masks - Requirements and test methods

Masques à usage médical - Exigences et méthodes  
d'essai

Medizinische Gesichtsmasken - Anforderungen und  
Prüfverfahren

This European Standard was approved by CEN on 19 November 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

<b>Contents</b>	<b>Page</b>
European foreword.....	4
Introduction .....	5
1 Scope.....	6
2 Normative references.....	6
3 Terms and definitions .....	6
4 Classification.....	8
5 Requirements.....	8
5.1 General.....	8
5.1.1 Materials and construction.....	8
5.1.2 Design.....	8
5.2 Performance requirements.....	8
5.2.1 General.....	8
5.2.2 Bacterial filtration efficiency (BFE).....	8
5.2.3 Breathability.....	8
5.2.4 Splash resistance.....	8
5.2.5 Microbial cleanliness (Bioburden) .....	9
5.2.6 Biocompatibility.....	9
5.2.7 Summary of performance requirements.....	9
6 Marking, labelling and packaging.....	9
Annex A (informative) Information for users.....	11
Annex B (normative) Method for <i>in vitro</i> determination of bacterial filtration efficiency (BFE) .....	12
B.1 General.....	12
B.2 Principle .....	12
B.3 Reagents and materials.....	12
B.3.1 General.....	12
B.3.2 Tryptic soy agar .....	12
B.3.3 Tryptic soy broth.....	12
B.3.4 Peptone water .....	13
B.3.5 Culture of <i>Staphylococcus aureus</i> ATCC 6538, growing on tryptic soy agar slants.....	13
B.4 Test apparatus.....	13
B.4.1 Six stage cascade impactor, the arrangement is specified in Table B.1. ....	13
B.4.2 Nebulizer, capable of delivering particles with a mean size of $(3,0 \pm 0,3) \mu\text{m}$ when in contact with the cascade impactor. ....	13
B.4.3 Aerosol chamber, glass, 600 mm long and 80 mm in external diameter.....	13
B.4.4 Flow meters, capable of measuring a flow rate of 28,3 l/min.....	13
B.4.5 Pressure gauge, capable of measuring a pressure of 35 kPa to an accuracy of $\pm 1$ kPa. ....	13

<b>B.4.6</b>	<b>Erlenmeyer flasks, 250 ml and 500 ml capacity.....</b>	<b>13</b>
<b>B.4.7</b>	<b>Peristaltic or syringe pump, capable of delivering 0,01 ml/min.....</b>	<b>13</b>
<b>B.4.8</b>	<b>Vacuum pump, capable of maintaining a flow rate of 57 l/min.....</b>	<b>13</b>
<b>B.5</b>	<b>Test specimens .....</b>	<b>13</b>
<b>B.6</b>	<b>Preparation of bacterial challenge.....</b>	<b>13</b>
<b>B.7</b>	<b>Procedure.....</b>	<b>14</b>
<b>B.8</b>	<b>Calculation of bacterial filtration efficiency (BFE) .....</b>	<b>16</b>
<b>B.9</b>	<b>Test report .....</b>	<b>16</b>
	<b>Annex C (normative) Method for determination of breathability (differential pressure) .....</b>	<b>18</b>
<b>C.1</b>	<b>Principle.....</b>	<b>18</b>
<b>C.2</b>	<b>Test apparatus .....</b>	<b>19</b>
<b>C.2.1</b>	<b>Mass flow meter(s) capable of measuring an airflow of 8 l/min.....</b>	<b>19</b>
<b>C.2.2</b>	<b>Manometer, a differential manometer (water or digital). Individual manometers can also be used. M1 is for the upstream pressure measurement and M2 is for the downstream pressure measurement. ....</b>	<b>19</b>
<b>C.2.3</b>	<b>Electric vacuum pump including a pressure buffer tank.....</b>	<b>19</b>
<b>C.2.4</b>	<b>Valve permitting the adjustment of the flow rate.....</b>	<b>19</b>
<b>C.2.5</b>	<b>Sample holder .....</b>	<b>19</b>
<b>C.3</b>	<b>Test specimens .....</b>	<b>19</b>
<b>C.4</b>	<b>Procedure.....</b>	<b>20</b>
<b>C.5</b>	<b>Calculation of differential pressure .....</b>	<b>20</b>
<b>C.6</b>	<b>Test report .....</b>	<b>20</b>
	<b>Annex D (informative) Microbial cleanliness.....</b>	<b>21</b>
<b>D.1</b>	<b>Sampling .....</b>	<b>21</b>
<b>D.2</b>	<b>Testing.....</b>	<b>21</b>
	<b>Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [1993 OJ L 169] aimed to be covered .....</b>	<b>22</b>
	<b>Bibliography .....</b>	<b>23</b>

## EN 14683:2019 (E)

### European foreword

This document (EN 14683:2019) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 14683:2014.

This document has been prepared under a standardization request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The main changes compared to the previous edition are:

- a) the appropriate method for *in vitro* determination of bacterial filtration efficiency (BFE) provided in Annex B has been updated;
- b) the former deleted note in 5.2.3 on the breathability requirements has been reintroduced as standard text; it provides a recommendation regarding the use of a respiratory protective device;
- c) the performance requirements on the breathability (differential pressure) provided in Table 1 have been increased and the appropriate method for determination provided in Annex C has been completely reviewed;
- d) the determination of the microbial cleanliness (bioburden) has been slightly updated and moved from 5.2.5 to a new informative Annex D.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



## **Introduction**

The transmission of infective agents during surgical procedures in operating theatres and other medical settings can occur in several ways. Sources are, for example, the noses and mouths of members of the surgical team. 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.

## EN 14683:2019 (E)

### 1 Scope

This document specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

This European Standard is not applicable to masks intended exclusively for the personal protection of staff.

NOTE 1 Standards for masks for use as respiratory personal protective equipment are available.

NOTE 2 Annex A provides information for the users of medical face masks.

### 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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)*

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

#### 3.1

##### **aerosol**

gaseous suspension of solid and/or liquid particles

#### 3.2

##### **bacterial filtration efficiency**

##### **BFE**

efficiency of the medical face mask material(s) as a barrier to bacterial penetration

Note 1 to entry: The BFE test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials.

#### 3.3

##### **biocompatibility**

quality of being accepted in a specific living environment without adverse or unwanted side effects

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
  - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-