



NSAI
Standards

Irish Standard
I.S. EN 14683:2019+AC:2019

Medical face masks - Requirements and test methods

© CEN 2019 No copying without NSAI permission except as permitted by copyright law.

I.S. EN 14683:2019+AC: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+AC:2019

Published:

2019-08-07

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

2019-08-25

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+AC:2019 is the adopted Irish version of the European Document EN 14683:2019+AC: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 is a free 6 page sample. Access the full version online.

This page is intentionally left blank

EUROPEAN STANDARD

EN 14683:2019+AC

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2019

ICS 11.140

English Version

Medical face masks - Requirements and test methods

Masques à usage médical - Exigences et méthodes
d'essaiMedizinische Gesichtsmasken - Anforderungen und
Prüfverfahren

This European Standard was approved by CEN on 19 November 2018 and includes Corrigendum AC 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, 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**

Contents

Page

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 ± 1 kPa.	13

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

**I.S. EN 14683 : 2019 : INC : AC : 2019 : EN :
COMBINED PDF**

- ⊙ Looking for additional Standards? Visit SAI Global Infostore
- ⊙ Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation

Need to speak with a Customer Service Representative - Contact Us