# SS 669 : Part 2 : 2020
## EN 14683:2019+AC:2019, IDT
(ICS 11.140)

**SINGAPORE STANDARD**

# Medical face masks

## – Part 2 : Requirements and test methods

(This national standard is the identical implementation of EN 14683:2019+AC:2019 and is adopted with permission of CEN, Rue de la Science 23 B - 1040 Brussels)

Singapore Standards Council

**SS 669 : Part 2 : 2020**
EN 14683:2019+AC:2019, IDT
(ICS 11.140)

SINGAPORE STANDARD

# Medical face masks

– Part 2 : Requirements and test methods

Published by Enterprise Singapore



ISBN 978-981-49-2541-9

The content of this Singapore Standard was approved on 10 December 2020 by the Biomedical and Health Standards Committee (BHSC) under the purview of the Singapore Standards Council.

First published, 2021

BHSC consists of the following members:

| | | Name | Representation |
|---|---|---|---|
| **Chairman** | : | Dr Yong Chern Chet | *Individual Capacity* |
| **Deputy Chairmen** | : | Mr Vincent Cheung | *Individual Capacity* |
| | | Adj Asst Prof Selina Seah | *Changi General Hospital* |
| | | Ms Wong Woei Jiuang | *Health Sciences Authority* |
| **Advisor** | : | Ms Jacqueline Monteiro | *Individual Capacity* |
| **Secretary** | : | Mr Kevin Tan | *Singapore Manufacturing Federation – Standards Development Organisation* |
| **Members** | : | Mr Abel Ang | *Advanced MedTech Holdings* |
| | | Mr Terri Chin | *Singapore Manufacturing Federation (Testing, Inspection and Certification Interest Group)* |
| | | Mr Alec Chow Boon Kuan | *Medtronic International Ltd* |
| | | Assoc Prof Raymond Chua | *Ministry of Health* |
| | | Ms Heidi Goh | *Singapore Manufacturing Federation (Medical Technology Industry Group)* |
| | | Prof James Goh | *Biomedical Engineering Society (Singapore)* |
| | | Dr Joel Lee | *Nanyang Polytechnic* |
| | | Mr Lee Suen Ming | *Parkway East Hospital* |
| | | Dr Daniel Li | *Integrated Health Information Systems Pte Ltd* |
| | | Ms Audrey Lok | *Enterprise Singapore* |
| | | Dr Margam Chandrasekaran | *Individual Capacity* |
| | | Dr Ong Siew Hwa | *Acumen Research Laboratories Pte Ltd* |
| | | Dr Jipson Quah | *Singapore Medical Association* |
| | | Dr Subramanian Venkatraman | *National University of Singapore (Industry Liaison Office)* |
| | | Dr Sidney Yee | *Diagnostics Development Hub – Accelerate Technologies Pte Ltd* |
| | | Dr Adrian Yeo | *Association of Biomedical Laboratory Professionals (Singapore)* |

BHSC set up the Technical Committee on Medical Devices to oversee the preparation of this standard. The Technical Committee consists of the following members:

| | | Name | Representation |
|---|---|---|---|
| **Chairman** | : | Prof James Goh | *Individual Capacity* |
| **Secretary** | : | Mr Kevin Tan | *Singapore Manufacturing Federation – Standards Development Organisation* |
| **Members** | : | Mr Chen Xiang | *Biosensors International Group* |
| | | Ms Chua Chui Khim | *Becton Dickinson Medical Products Pte Ltd* |
| | | Dr Christopher Lam | *Health Sciences Authority* |
| | | Assoc Prof Leo Hwa Liang | *National University Singapore* |
| | | Dr Lim Jing | *Osteopore International Pte Ltd* |
| | | Ms Iris Tan | *Individual Capacity* |

(blank page)

## Contents

**Page**

National Foreword ..... 7
Introduction ..... 8
1 Scope ..... 9
2 Normative references ..... 9
3 Terms and definitions ..... 9
4 Classification ..... 11
5 Requirements ..... 11
5.1 General ..... 11
5.1.1 Materials and construction ..... 11
5.1.2 Design ..... 11
5.2 Performance requirements ..... 11
5.2.1 General ..... 11
5.2.2 Bacterial filtration efficiency (BFE) ..... 11
5.2.3 Breathability ..... 12
5.2.4 Splash resistance ..... 12
5.2.5 Microbial cleanliness (Bioburden) ..... 12
5.2.6 Biocompatibility ..... 12
5.2.7 Summary of performance requirements ..... 13
6 Marking, labelling and packaging ..... 13
Annex A (informative) Information for users ..... 14
Annex B (normative) Method for in vitro determination of bacterial filtration efficiency (BFE) ..... 16
B.1 General ..... 16
B.2 Principle ..... 16
B.3 Reagents and materials ..... 16
B.3.1 General ..... 16
B.3.2 Tryptic soy agar ..... 16
B.3.3 Tryptic soy broth ..... 16
B.3.4 Peptone water ..... 17
B.3.5 Culture of Staphylococcus aureus ATCC 6538, growing on tryptic soy agar slants ..... 17
B.4 Test apparatus ..... 17
B.4.1 Six stage cascade impactor, the arrangement is specified in Table B.1 ..... 17
B.4.2 Nebulizer, capable of delivering particles with a mean size of (3,0 ± 0,3) µm when in contact with the cascade impactor ..... 17
B.4.3 Aerosol chamber, glass, 600 mm long and 80 mm in external diameter ..... 17
B.4.4 Flow meters, capable of measuring a flow rate of 28,3 l/min ..... 17

B.4.5 Pressure gauge, capable of measuring a pressure of 35 kPa to an accuracy of ± 1 kPa.....17
B.4.6 Erlenmeyer flasks, 250 ml and 500 ml capacity .....17
B.4.7 Peristaltic or syringe pump, capable of delivering 0,01 ml/min.....17
B.4.8 Vacuum pump, capable of maintaining a flow rate of 57 l/min.....17
B.5 Test specimens.....17
B.6 Preparation of bacterial challenge.....17
B.7 Procedure.....18
B.8 Calculation of bacterial filtration efficiency (BFE).....20
B.9 Test report.....20
Annex C (normative) Method for determination of breathability (differential pressure).....22
C.1 Principle.....22
C.2 Test apparatus .....23
C.3 Test specimens.....23
C.4 Procedure.....24
C.5 Calculation of differential pressure.....24
C.6 Test report.....24
Annex D (informative) Microbial cleanlines.....26
D.1 Sampling.....26
D.2 Testing.....26
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.....27
Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [1993 OJ L 169].....27
Bibliography.....29

## National Foreword

This Singapore Standard was prepared by the Technical Committee on Medical Devices under the purview of BHSC.

SS 669 consists of the following five parts, under the general title 'Medical face masks':

- Part 1: Filtering half masks to protect against particles – Requirements, testing, marking (Identical adoption of EN 149:2001+A1:2009)
- Part 2: Requirements and test methods (Identical adoption of EN 14683:2019+AC:2019)
- Part 3: Standard specification for performance of materials used in medical face masks (Identical adoption of ASTM F2100-19)
- Part 4: Standard test method for evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of Staphylococcus aureus (Identical adoption of ASTM F2101-19)
- Part 5: Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres [Identical adoption of ASTM F2299 / F2299M-03(2017)]

This standard is an identical adoption of EN 14683:2019+AC:2019, "Medical face masks – Requirements and test methods", including its Amendment, published by the European Committee for Standardisation, CEN, Avenue Marnix 17, B-1000 Brussels.

NOTE 1 – Where appropriate, the words "European Standard" are read as "Singapore Standard".

NOTE 2 – Reference to European Standards are replaced by applicable Singapore Standards/Technical References.

NOTE 3 – Where numerical values are expressed as decimals, the comma is read as a full point.

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

**NOTE**

1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions. Where SSs are deemed to be stable, i.e. no foreseeable changes in them, they will be classified as "Mature Standards". Mature Standards will not be subject to further review, unless there are requests to review such standards.*

2. *An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore and the Singapore Standards Council shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR. Although care has been taken to draft this standard, users are also advised to ensure that they apply the information after due diligence.*

3. *Compliance with a SS or TR does not exempt users from any legal obligations.*

## 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.

# Medical face masks – Part 2: Requirements and test methods

## 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)*