**SS 669-3:2021**
**ASTM F2100-21, IDT**
(ICS 11.140)

**SINGAPORE STANDARD**

# Medical face masks

## – Part 3 : Standard specification for performance of materials used in medical face masks



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## National Foreword

This Singapore Standard was prepared by the Technical Committee on Medical Devices under the purview of the Biomedical and Health Standards Committee (BHSC).

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SS 669-3:2021 is a revision and will replace SS 669-3:2020.

NOTE – Reference to International Standards are replaced by applicable Singapore Standards or Technical References.

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.*

Designation: F2100 – 21

# Standard Specification for Performance of Materials Used in Medical Face Masks[1]

This standard is issued under the fixed designation F2100; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This specification covers testing and requirements for materials used in the construction of medical face masks that are used in providing healthcare services such as surgery and patient care.

1.1.1 This specification addresses medical masks with ties (surgical masks) and ear loops (procedure masks or isolation masks).

1.2 This specification provides for the classification of medical face mask material performance. Medical face mask material performance is based on testing for bacterial filtration efficiency, differential pressure, sub-micron particulate filtration efficiency, resistance to penetration by synthetic blood, and flammability.

1.3 This specification does not address all aspects of medical face mask design and performance. This specification does not specifically evaluate the effectiveness of medical face mask designs as related to their overall barrier and breathability properties.

1.3.1 This specification does not include any specific design criteria for medical face masks; however, surgical masks are differentiated by having ties to allow adjustment of the medical face mask fit in comparison to procedure or isolation masks, which use ear loops to affix the mask to the wearer's face.

1.4 This specification does not address requirements for regulated respiratory protection devices such as respirators, which may be necessary for some healthcare services and exposure to inhalation hazards.

NOTE 1—Performance requirements for NIOSH-approved N95 respirators are described in 42 CFR Part 84. Additional requirements for NIOSH-approved N95 respirators intended for use in healthcare settings are described in the Memorandum of Understanding between FDA and NIOSH. FDA/NIOSH MOU 225-18-006, November 2017 and the NIOSH Conformity Assessment Letter to Manufacturers, NIOSH CA 2018-1010, November 2018.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 The following precautionary caveat pertains only to the test methods portion, Section 9, of this specification: *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

## 2. Referenced Documents

2.1 *ASTM Standards:*[2]

F1494 Terminology Relating to Protective Clothing

F1862 Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

F2101 Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*

F2299 Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres

F3050 Guide for Conformity Assessment of Personal Protective Clothing and Equipment

2.2 *ANSI/ASQC Standard:*[3]

ANSI/ASQC Z1.4 Sampling Procedures and Tables for Inspection by Attributes

2.3 *ISO Standards:*[4]

ISO 2859-1 Sampling Plans for Inspection by Attributes

[1] This specification is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.40 on Biological.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

ISO 10993-1 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process
ISO 10993-5 Biological Evaluation of Medical Devices—Part 5: Tests for in vitro Cytotoxicity
ISO 10993-10 Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Skin Sensitization
ISO 10993-23 Biological Evaluation of Medical Devices—Part 23: Tests for Irritation
ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories
ISO/IEC 17026 Conformity Assessment—Example of a Certification Scheme for Tangible Products

2.4 *European Standard:*[5]

EN 14683 Medical Face Masks—Requirements and Test Methods

2.5 *Federal Standards:*[6]

16 CFR Part 1610 Standard for the Flammability of Clothing Textiles
21 CFR Section 878.4040 Surgical Apparel
29 CFR Part 1910.1030 Occupational Exposure to Blood-Borne Pathogens: Final Rule
42 CFR Part 84 Approval of Respiratory Protective Devices

[5] Available from British Standards Institution (BSI), 389 Chiswick High Rd., London W4 4AL, U.K., http://www.bsigroup.com.

[6] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.