SS 669 : Part 3 : 2020
ASTM F2100-19, 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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Contents

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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)]

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

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Medical face masks – Part 3: Standard specification for performance of materials used in medical face masks[1]

ε[1] NOTE—A typo in 2.4 was corrected editorially in April 2020.

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.

1.2 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 the barrier and breathability properties. This specification does not apply to regulated respiratory protection, which may be necessary for some healthcare services.

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

1.5 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.

1.6 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:*

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

[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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2.2 *ANSI/ASQC Standard:*

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

2.3 *ISO Standard:*

ISO 2859-1 Sampling Plans for Inspection by Attributes

2.4 *European Standard:*

EN 14683 Medical Face Masks—Requirements and Test Methods

2.5 *Federal Standards:*

16 CFR Part 1610 Standard for the Flammability of Clothing Textiles

29 CFR Part 1910.1030 Occupational Exposure to Blood- borne Pathogens: Final Rule

42 CFR Part 84 Approval of Respiratory Protective Devices

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