SS 669 : Part 4 : 2020
ASTM F2101-19, IDT
(ICS 11.140)

SINGAPORE STANDARD

Medical face masks

– Part 4 : Standard test method for evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of Staphylococcus aureus

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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.

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

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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)]

This standard is an identical adoption of ASTM F2101-19, "Standard test method for evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of Staphylococcus aureus", copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428, USA. Reprinted by permission of ASTM International.

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

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Medical face masks – Part 4: Standard test method for evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of Staphylococcus aureus[1]

INTRODUCTION

Workers, primarily those in the healthcare profession involved in treating and caring for individuals injured or sick, as well as the patient, can be exposed to biological aerosols capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential of airborne exposure through the use of medical face masks.

1. Scope

1.1 This test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials, employing a ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of medical face mask materials.

1.2 This test method is a quantitative method that allows filtration efficiency for medical face mask materials to be determined. The maximum filtration efficiency that can be determined by this method is 99.9 %.

1.3 This test method does not apply to all forms or conditions of biological aerosol exposure. Users of the test method should review modes for worker exposure and assess the appropriateness of the method for their specific applications.

1.4 This test method evaluates medical face mask materials as an item of protective clothing but does not evaluate materials for regulatory approval as respirators. If respiratory protection for the wearer is needed, a NIOSH-certified respirator should be used. Relatively high bacterial filtration efficiency measurements for a particular medical face mask material does not ensure that the wearer will be protected from biological aerosols, since this test method primarily evaluates the performance of the composite materials used in the construction of the medical face mask and not its design, fit, or facial-sealing properties.

1.5 *Units*—The values stated in SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance of the standard.

1.6 This test method does not address breathability of the medical face mask materials or any other properties affecting the ease of breathing through the medical face mask material.

1.7 This test method may also be used to measure the bacterial filtration efficiency (BFE) of other porous medical products such as surgical gowns, surgical drapes, and sterile barrier systems.

1.8 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 deter- mine the applicability of regulatory limitations prior to use.

[1] This test method 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.
Current edition approved July 1, 2019. Published July 2019. Originally approved in 2001. Last previous edition approved in 2014 as F2101 – 14. DOI: 10.1520/ F2101-19.

1.9 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:

E171/E171M Practice for Conditioning and Testing Flexible Barrier Packaging

F1494 Terminology Relating to Protective Clothing

2.2 ANSI/ASQ Standard:

ANSI/ASQ 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 Military Standard:

MIL-STD 36954C (1973) Military Specification: Mask, Surgical, Disposable