

SS 669 : Part 5 : 2020
ASTM F2299 / F2299M-03(2017), IDT
(ICS 11.120.20)

SINGAPORE STANDARD

Medical face masks

– Part 5 : Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres

[This national standard is an identical adoption of ASTM F2299 / F2299M-03(2017), copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428, USA]

SS 669 : Part 5 : 2020

ASTM F2299 / F2299M-03(2017), IDT
(ICS 11.120.20)

SINGAPORE STANDARD

Medical face masks

– Part 5 : Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres

Published by Enterprise Singapore

All rights reserved. Unless otherwise specified, no part of this Singapore Standard may be reproduced or utilised in any form or by any means, electronic or mechanical, including photocopying and microfilming, without permission in writing from Enterprise Singapore. Request for permission can be sent to: standards@enterprisesg.gov.sg.

© ASTM 2017

© Enterprise Singapore 2020

ISBN 978-981-49-2544-0

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

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	<i>Individual Capacity</i>
Secretary	: Mr Kevin Tan	<i>Singapore Manufacturing Federation – Standards Development Organisation</i>
Members	: Mr Chen Xiang	<i>Biosensors International Group</i>
	Ms Chua Chui Khim	<i>Becton Dickinson Medical Products Pte Ltd</i>
	Dr Christopher Lam	<i>Health Sciences Authority</i>
	Assoc Prof Leo Hwa Liang	<i>National University Singapore</i>
	Dr Lim Jing	<i>Osteopore International Pte Ltd</i>
	Ms Iris Tan	<i>Individual Capacity</i>

(blank page)

Contents

	Page
National Foreword.....	6
1. Scope	7
2. Referenced documents.....	7
3. Terminology.....	8
4. Summary of test method	8
5. Significance and use	8
6. Apparatus	9
7. System preparation and control	9
8. Number of downstream/upstream sampling intervals.....	14
9. Material specimen selection and conditioning	15
10. Test procedure	16
11. Calculations	17
12. Report.....	18
13. Precision and bias	19
14. Keywords.....	21

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 F2299 / F2299M-03(2017), "Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres", copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428, USA. Reprinted by permission of ASTM International.

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.*

Medical face masks – Part 5: Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres¹

1. Scope

1.1 This test method establishes procedures for measuring the initial particle filtration efficiency of materials used in medical facemasks using monodispersed aerosols.

1.1.1 This test method utilizes light scattering particle counting in the size range of 0.1 to 5.0 µm and airflow test velocities of 0.5 to 25 cm/s.

1.2 The test procedure measures filtration efficiency by comparing the particle count in the feed stream (upstream) to that in the filtrate (downstream).

1.3 The values stated in SI units or in other units shall be regarded separately as standard. The values stated in each system must be used independently of the other, without combining values in any way.

1.4 The following precautionary caveat pertains only to the test methods portion, Section 10, 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 and health practices and determine the applicability of regulatory limitations prior to use.*

1.5 *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:

D1356 Terminology Relating to Sampling and Analysis of Atmospheres

D1777 Test Method for Thickness of Textile Materials D2905 Practice for Statements on Number of Specimens for Textiles (Withdrawn 2008)

D3776/D3776M Test Methods for Mass Per Unit Area (Weight) of Fabric

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

F50 Practice for Continuous Sizing and Counting of Air-borne Particles in Dust-Controlled Areas and Clean Rooms Using Instruments Capable of Detecting Single Sub-Micrometre and Larger Particles

F328 Practice for Calibration of an Airborne Particle Counter Using Monodisperse Spherical Particles (Withdrawn 2007)

F778 Methods for Gas Flow Resistance Testing of Filtration Media

F1471 Test Method for Air Cleaning Performance of a High-Efficiency Particulate Air Filter System

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 June 1, 2017. Published June 2017. Originally approved in 2003. Last previous edition approved in 2010 as F2299/F2299M – 03 (2010). DOI: 10.1520/F2299_F2299M-03R17.

F1494 Terminology Relating to Protective Clothing

F2053 Guide for Documenting the Results of Airborne Particle Penetration Testing of Protective Clothing Materials