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

3. Terminology

3.1 *Definitions:*

3.1.1 *bacterial filtration efficiency (BFE), n*—the effectiveness of medical face mask material in preventing the passage of aerosolized bacteria, expressed in the percentage of a known quantity that does not pass the medical face mask material at a given aerosol flow rate.

3.1.2 *body fluid, n*—any liquid produced, secreted, or excreted by the human body.

3.1.2.1 *Discussion*—In this specification, body fluids include liquids potentially infected with blood-borne pathogens, including, but not limited to: blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid and peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids (see 29 CFR Part 1910.1030).

3.1.3 *body fluid simulant, n*—a liquid which is used to act as a model for human body fluids.

3.1.4 *differential pressure, n*—the measured pressure drop across a medical face mask material.

3.1.4.1 *Discussion*—In this specification, differential pressure is expressed as a force per unit area.

3.1.5 *flammability, n*—those characteristics of a material that pertain to its relative ease of ignition and relative ability to sustain combustion.

3.1.6 *isolation mask, n*—another name for a procedure mask, particularly in reference to ear loop masks worn by patients.

3.1.7 *medical face mask, n*—an item of protective clothing designed to protect portions of the wearer's face, including the mucous membrane areas of the wearer's nose and mouth, from contact with blood and other body fluids during medical procedures.

3.1.7.1 *Discussion*—Examples of medical face masks include surgical masks, procedure masks, isolation masks, laser masks, dental masks, and patient care masks.

3.1.8 *penetration, n*—in a protective clothing material or item, the flow of a chemical on a non-molecular level through closures, porous materials, seams and pinholes, or other imperfections in protective clothing.

3.1.8.1 *Discussion*—In this specification, blood or body fluids replace the term chemical and the specific penetration liquid is synthetic blood, a body fluid simulant.

3.1.9 *procedure mask, n*—a medical face mask that is used for performing patient procedures, or when patients are in isolation to protect them or their surroundings from potential contaminants.

3.1.9.1 *Discussion*—Procedure masks are used to protect both patients and staff from the transfer of respiratory secretions, fluids, or other debris. Procedure masks are used for generally "respiratory etiquette" to prevent clinicians, patients, and visitors from spreading germs by talking, coughing, or sneezing. They may also be used for source control. Procedure masks have ear loops for easier donning and doffing.

3.1.10 *protective clothing, n*—an item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard; or, isolating the external environment from contamination by the wearer of the clothing.

3.1.10.1 *Discussion*—The primary purpose of protective clothing is to act as a barrier for the wearer to a hazard. However, the product may also offer protection as a barrier which prevents the body from being a source of contamination.

3.1.11 *respirator, n*—a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling airborne hazards such as particles, gases, or vapors. Respirators are regulated devices and must be approved by the applicable agency, such as the National Institute for Occupational Safety and Health (NIOSH), in accordance with the specific regulation in 42 CFR Part 84.

3.1.11.1 *Discussion*—Healthcare workers can be instructed to wear disposable half-mask filtering facepiece respirators with N95 or higher levels of filtration efficiency as defined in

[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.

42 CFR Part 84 in situations with an elevated risk of exposure to airborne pathogenic biological particulates. See also definition for *surgical N95 respirator*.

3.1.12 *source control, n*—the use of a medical face mask or other device covering the wearer's nose and mouth that is primarily intended to contain the wearer's respiratory secretions to help prevention the transmission from infected individuals who may or may not have symptoms of a specific respiratory disease.

3.1.12.1 *Discussion*—Medical faces masks provide a level of source control when worn properly and meeting the requirements in this specification.

3.1.13 *sub-micron particulate filtration efficiency, n*—the efficiency of the filter material in capturing aerosolized particles smaller than one micron, expressed as the percentage of a known number of particles that do not pass through the medical face mask material at a given flow rate or face velocity.

3.1.14 *surgical mask, n*—a medical face mask that is used inside the operating room or within other sterile procedure areas to protect the patient environment from contamination.

3.1.14.1 *Discussion*—Surgical masks also protect the clinician from contaminated fluid or debris generated during the procedure. Surgical masks have ties so that they can be adjusted for fit, and are tied over top of a surgical cap or a bouffant cap.

3.1.15 *surgical N95 respirator, n*—a respirator that is approved by NIOSH and is cleared by the U.S. Food and Drug Administration (FDA) as a Class II medical device under 21 CFR Section 878.4040.

3.1.15.1 *Discussion*—Surgical N95 respirators are N95 disposable filtering facepiece respirators that are approved under 42 CFR Part 84 criteria and meet additional performance criteria for material biocompatibility, fluid resistance, and flammability as required by the FDA.

3.1.16 *synthetic blood, n*—a mixture of a red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and some other body fluids, and the color of blood.

3.1.16.1 *Discussion*—The synthetic blood in this test method does not simulate all of the characteristics of blood or body fluids, for example, polarity (wetting characteristics), coagulation, or content of cell matter.

3.2 For definitions of other protective clothing-related terms used in this test method, refer to Terminology F1494.

4. Significance and Use

4.1 This specification covers the minimum performance requirements for materials used in the construction of medical face masks.

4.1.1 For the purposes of this specification, medical face masks include surgical masks and procedure masks.

4.2 This specification provides classification of performance for a range of medical face mask materials. Medical face mask performance classes are based on the barrier performance properties of the medical face mask materials (fluid resistance, bacterial filtration efficiency, and sub-micron filtration efficiency). The list of specified properties represents industry practices for characterizing material performance, but does not include all aspects of performance that may be necessary to protect healthcare workers. Therefore, this specification does not cover medical face masks for all possible use situations. For example, the Centers for Disease Control and Prevention (CDC) specifically recommends NIOSH respirators that are at least 95 % efficient for tuberculosis exposure control.[7]

NOTE 2—This specification does not provide specific criteria for demonstrating medical face mask protection of the patient.

NOTE 3—The level of protection provided by medical face masks depends on several factors not considered in this specification. Examples include facial fit and material degradation from wearer challenges (perspiration, talking, sneezing, and the length of time the medical face mask is worn).

4.3 Users of this specification are cautioned that improved resistance of medical face masks to penetration by synthetic blood can cause a reduction in medical face mask breathability. In general, increasing synthetic blood penetration resistance (and bacterial filtration efficiency and sub-micron particulate filtration efficiency) results in increasing pressure drop or reduction of breathability for medical face masks of the same design.

4.4 This specification is intended to provide the function of source control for materials used in the construction medical face masks, but does not include any specific criteria that relate to the design and fit of medical face masks on individual wearers that allows an assessment of overall medical face mask source control effectiveness.

4.5 This specification (or its requirements) does not evaluate medical face masks for regulatory approval as respirators. It specifically only evaluates the materials used in the construction of the medical face mask and not the seal of the medical face mask against the wearer's face or other design features that determine its effectiveness of preventing particle or liquid exposure to the wearer. If respiratory protection for the wearer is needed, a NIOSH-certified respirator meeting the requirements of 42 CFR Part 84 should be used.

4.6 The selection of the appropriate medical face mask must be governed by the potential exposure hazards based on the specific areas of performance associated with class of medical face masks. General-use masks provide minimal fluid resistance and are suitable for situations such as in isolation settings and for certain types of patient care. Where procedures involve the generation of sub-micron particles, such as in laser or electrocautery surgery, sub-micron filtering masks are appropriate. Where procedures involve the probability or likely exposure to blood or body fluids, select fluid-resistant medical faces masks.

5. Classification

5.1 Medical face mask materials covered under this specification shall be designated as one or more of the following

[7] Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings, 2005, CDC.