Designation: F2100 – 23

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*

F3050 Guide for Conformity Assessment of Personal Protective Clothing and Equipment

F3502 Specification for Barrier Face Coverings

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

ISO 10993-1 Biological Evaluation of Medical Devices—

[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.

Current edition approved March 1, 2023. Published March 2023. Originally approved in 2001. Last previous edition approved in 2021 as F2100 – 21. DOI: 10.1520/F2100-23.

[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.

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 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

[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.