Designation: F 2100 – 01

Standard Specification for Performance of Materials Used in Medical Face Masks[1]

This standard is issued under the fixed designation F 2100; 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 health care 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 also apply to respiratory protection, which may be necessary for some health care services.

1.4 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.

1.5 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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

F 1215 Test Method for Determining the Initial Efficiency of a Flatsheet Filter Medium in an Airflow Using Latex Spheres[2]

F 1494 Terminology Relating to Protective Clothing[3]

F 1862 Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)[3]

F 2101 Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*[3]

2.2 *ANSI/ASQC Standard:*[4]

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

2.3 *ISO Standard:*[5]

ISO 2859-1 Sampling Plans for Inspection by Attributes

2.4 *Military Standard:*[6]

MIL-M-36954C Military Specification, Mask, Surgical, Disposable

2.5 *Federal Standards:*[7]

16 CFR Part 1610 Standard for the Flammability of Clothing Textiles

29 CFR Part 1910.1030 Occupational Exposure to Bloodborne 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, and 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.

[1] This specification is under the jurisdiction of ASTM Committee F23 on Protective Clothing and is the direct responsibility of Subcommittee F23.40 on Biological.

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[2] Discontinued; see *1999 Annual Book of ASTM Standards*, Vol 14.04.

[3] *Annual Book of ASTM Standards*, Vol 11.03.

[4] Available from American Society for Quality Control, 611 East Wisconsin Ave., Milwaukee, WI 53202.

[5] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[6] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

[7] Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.