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Face Masks Particulate Filtration Efficiency PFE Tester

Product No: GLE-20

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GLE-20 is an oil-salt two-in-one Face Masks Particulate Filtration Efficiency PFE Tester. According to ASTM F1862-17, ASTM F2299-(, ASTM F2100-2019, BS EN14683-2019, BS EN 14387-2004+A1 2008, BS EN 136-1998, BS EN 140-1999, BS EN 143-2000 +C1-A1, BS EN 149-

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Standards:

1. It is designed and manufactured according to YY0469-2004 "Technical Requirements for Medical Surgical Masks" and GB2626-2006 "Respiratory Protective Equipment Self-Suction Filter Anti-Particle Respirator". At the same time, it also refers to the advanced design concepts of similar international equipment (such as the American TSI company), based on the principle of " European standard EN1822-3: 1998 single-sheet filter material test ", but it is suitable for the test status of domestic related industries
2. GB / T 32610-2016 "Technical Specifications for Daily Protective Masks"
3. GB / T 19082-2009 "Technical requirements for medical disposable protective clothing"
4. GB / T 19083-2010 "Technical Requirements for Medical Protective Masks"
5. GB 24539-2009 General technical requirements for protective clothing and chemical protective clothing
6. YY / T 0969-2013 "Standard for disposable medical masks"

Standard Requirement:

Using sodium chloride particles to detect KN filter elements, and use dioctyl phthalate or equivalent oil particles (or paraffin oil) to detect KP filter elements.

Test according to 6.3

During the test, the filtration efficiency of each sample should always meet the requirements of Table 2

Tags : GLE-20 , Particulate filtration efficiency tester

KN95	95.0%	
KN100	99.97%	Not Siut
KP90		90.0%
KP95		95.0%
KP100	Not Suit	99.97%

Specifications:

1. Filtration efficiency detection flowmeter range: (10 ~ 100) L / min, accuracy level 2.5
2. Filtration efficiency detection range: (0.001 ~999)%.
3. Filtering efficiency sampling frequency: 1-9999 times / min can be set arbitrarily.
4. Filtration efficiency Particulate concentration: (0.001-200) mg / m^3.
5. Differential pressure sensor range: 0 ~1000pa
6. Counting median diameter: salt particles (0.075 ±0.02) μm, oil particles (0.185 ± 0.02) μm. Geometric standard deviation of particle size distribution: salt particles≤1.86, oil particles≤1.60. Dynamic detection range: 0.001-100 mg / m^3, accuracy 1%.
7. Test area: 100cm^2.
8. Aerosol: NaCl (optionally with DOP, DEHS, paraffin oil, corn oil).
9. Aerosol concentration: 12-20mg / m^3 (Nacl), 50-200mg / m^3 (DOP).
10. The system contains two independent aerosol generators: oily and salty aerosol generators containing two particle counting sensors, one particle concentration sensor and one particle generator
11. Power: AC220V 50Hz(120V/60Hz can be customized)

GLE-20 Characteristics:

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1. The oil and salt two-in-one test and the two sets of test hardware systems are completely independent. The test does not interfere v other to ensure the accuracy of the oil and salt test.

6. Configure temperature and humidity sensor, real-time display of ambient temperature and humidity (temperature and humidity requirements: 25 ℃ ± 5 ℃, 30% RH ± 10% RH).
7. Equipped with glass rotor flowmeter, vacuum pump and gas electromagnetic flowmeter.
8. Control system: touch-screen computer and test software have been configured to automatically test gas concentration and filtration efficiency, save, output, query, copy and export test data, support A4 paper printing and small bill printing test results

公司名称： LISUN 公司地址： Shanghai

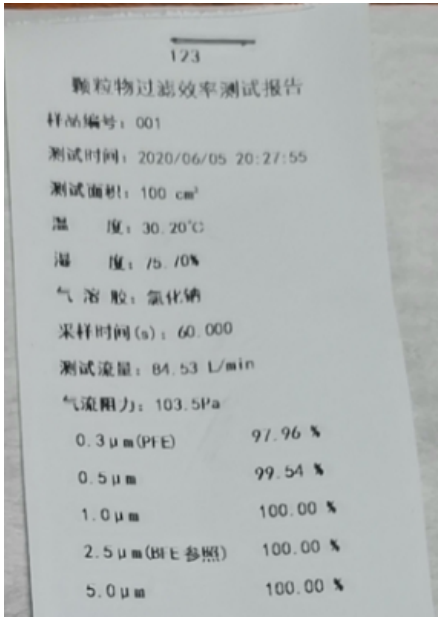
样品名称： 12306 样品编号： 002

测试人员： 测试标准： GB2626

测试时间： 2020/06/06 17:48:08 报告时间： 2020/06/06 17:50:40

测试条件			
测试面积：	100cm3	气溶胶：	油性 / 33.96 mg/m3
采样时间：	90	采样间隔：	2
测试流量：	94.80 L/min	气流阻力：	126.0Pa
温度（℃）：	29.00℃	湿度（%RH）：	84.40%

测试数据				
粒径	上游颗粒数	下游颗粒数	过滤效率（%）	穿透率（%）
0.3μm(PFE)	70914.00	573.00	99.19	0.81
0.5μm	15635.00	79.00	99.49	0.51
1.0μm	3320.00	3.00	99.91	0.09
2.5μm(BFE 参照)	230.00	0.00	100.00	0.00
5.0μm	2.00	0.00	100.00	0.00



检测员：_____ 审核人：_____ 复核人：_____

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Designation: F2100 – 19

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.

1.2 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 apply to regulated respiratory protection, which may be necessary for some healthcare services.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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

1.6 *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

2.2 *ANSI/ASQC Standard:*[3]

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

2.3 *ISO Standard:*[4]

ISO 2859-1 Sampling Plans for Inspection by Attributes

2.4 *European Standard:*[5]

EN 14683 Medical Fask Masks—Requirements and Test Methods

2.5 *Federal Standards:*[6]

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

[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.

[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.

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 pressure 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 *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.

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

3.1.7 *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.

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

3.1.8 *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.

3.1.8.1 *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.

3.1.9 *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 does not pass the medical face mask material at a given flow rate.

3.1.10 *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.

3.1.10.1 *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.

4.2 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 requires NIOSH respirators that are at least 95 % efficient for tuberculosis exposure control.

NOTE 1—This specification does not provide specific criteria for demonstrating medical face mask protection of the patient.

NOTE 2—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 (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.

4.5 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 performance classes as based on the barrier performance properties of the materials used in medical face masks: Level 1 barrier, Level 2 barrier, and Level 3 barrier.

5.1.1 Level 1 barrier medical face mask materials are evaluated for their ability to capture sub-micron particles, resistance to penetration by synthetic blood at the minimum velocity specified in Test Method F1862, bacterial filtration efficiency, and differential pressure.

5.1.2 Level 2 barrier medical face mask materials are evaluated for their ability to capture sub-micron particles and are evaluated for resistance to penetration by synthetic blood at the middle velocity specified in Test Method F1862, bacterial filtration efficiency, and differential pressure.

5.1.3 Level 3 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood at the maximum velocity specified in Test Method F1862, sub-micron particulate filtration, bacterial filtration efficiency, and differential pressure.

6. Requirements

6.1 The properties of the medical face mask material shall conform to the specifications requirements in Table 1, as tested in accordance with Section 9.

NOTE 3—Medical face mask materials comprise specimens taken from manufactured medical face masks, with all layers arranged in proper order.

6.2 Materials used in the construction of medical face masks shall meet the requirements for Class 1, normal flammability specified in 16 CFR Part 1610.

7. Sampling

7.1 Testing shall be performed on materials taken from manufactured medical face masks.

TABLE 1 Medical Face Mask Material Requirements by Performance Level

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial filtration efficiency, %	≥95	≥98	≥98
Differential pressure, mm H_2O/cm^2	<5.0	<6.0	<6.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥95	≥98	≥98
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	80	120	160
Flame spread	Class 1	Class 1	Class 1

7.2 An acceptable quality limit of 4 % shall be used for all required testing to establish conformance of medical face masks to a specific performance class.

7.3 Examples of acceptable sampling plans are found in ANSI/ASQC Z1.4 and ISO 2859-1.

8. Number of Tests

8.1 A sufficient number of medical face masks shall be evaluated for each test to achieve the established acceptable quality limit or confidence level.

9. Test Methods

9.1 *Bacterial Filtration Efficiency*—Determine the bacterial filtration efficiency as directed in Test Method F2101.

9.2 *Differential Pressure*—Determine breathing resistance or differential pressure as directed in EN 14683:2019, Annex C.

NOTE 4—This test method provides a measurement of pressure per unit area of material specimen tested.

9.3 *Sub-Micron Particulate Filtration*—Determine particulate filtration efficiency as directed in Test Method F2299.

9.4 *Resistance to Penetration by Synthetic Blood*—Determine synthetic blood penetration resistance as specified in Test Method F1862.

9.5 *Flammability*—Determine flammability as specified in 16 CFR Part 1610.

10. Report

10.1 The primary package containing the medical face masks that meet this specification shall be prominently labeled with the following information:

10.1.1 Manufacturer name,

10.1.2 Product or style name,

10.1.3 Product lot, and

10.1.4 A graphic representation indicating the performance level met in Table 1 with the technical requirements of the indicated performance level. The graphic representation shall include a prominent visual indication of the performance level.

11. Keywords

11.1 bacterial filtration efficiency; differential pressure; fluid resistance; general use; medical face masks; particle filtration efficiency; sub-micron filtration