Technical Guidance: **Medical / Surgical Face Masks**

Updated July 20, 2020

U.S. FDA regulatory info
Classification: Class II (special controls)
Product code: FXX (mask, surgical) [1]
Regulation number: 878.4040 (Surgical apparel) [2]

European Union regulatory info
Applicable regulation: 2016/425 on Personal Protective Equipment [3]

World Health Organization guidance
Personal protective equipment for COVID-19 [4]
Advice on the use of masks in the context of COVID-19 [5]

Overview

The purpose of this technical guidance document is to provide the following information:

- A general overview of the purpose of surgical/medical face masks as well as an explanation of the differences between medical face masks and respirators.
- A concise introduction to the key design features of medical face masks, including a brief explanation of why each feature is important and how it is tested
- An overview of applicable U.S. FDA and European Union regulatory requirements for medical face masks, followed by a set of recommended safety and effectiveness criteria that may be used to assess adequate safety and effectiveness

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Introduction and Intended Use

Overview

Surgical face masks are personal protective equipment (PPE) that are used to protect the wearer from airborne particles and from liquids that may contaminate the face. They are a relatively loose-fitting mask that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the surrounding environment. Although a surgical mask is meant to help block large droplets, splashes, sprays, or splatter (that may contain viruses and bacteria), they are not designed to block very small airborne particles [6].

The World Health Organization cautions that "the use of a mask alone is insufficient to provide an adequate level of protection or source control, and other personal and community level measures should also be adopted to suppress transmission of respiratory viruses. Whether or not masks are used, compliance with hand hygiene, physical distancing and other infection prevention and control (IPC) measures are critical to prevent human-to-human transmission of COVID-19 [5]."

Medical Face Masks vs. Respirators

There is sometimes confusion between medical face masks and respirators. The two types of PPE, as well as their corresponding intended and recommended uses, are described below.

Medical Face Mask

A medical face mask (also known as a surgical mask) is defined as a surgical or procedure mask that is subject to performance characteristics (set forth by standards ASTM F2100-19, EN 14683:2019, or equivalent) that aim to balance high filtration, adequate breathability, and optionally, fluid penetration resistance [5] [7] [8].

Figure 1 - Example Medical/Surgical Face Mask (https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/face-masks-and-surgical-masks-covid-19-manufacturing-purchasing-importing-and-donating-masks-during)

For **health workers or caregivers**, the World Health Organization recommends the use of a medical face mask for the following transmission scenarios, settings, and activities:

Table 1 - World Health Organization: Medical Face Mask Guidance for Use by Health Workers or Caregivers [5]

Transmission scenario	Who	Setting	Activity
Known or suspected community transmission	Health worker or caregiver	Health facility (including primary, secondary, tertiary care levels, outpatient care, and LTCF)	In patient care area – irrespective if patients are COVID-19 suspect/confirmed
	Health worker	Home visit (for example, for antenatal or postnatal care, or for a chronic condition)	When in direct contact or when a distance of at least 1m cannot be maintained.
Sporadic transmission or clusters of COVID-19 cases	Health worker or caregiver	Health care facility (including primary, secondary, tertiary care levels, outpatient care, and LTCF)	Providing any patient care

Transmission scenario	Who	Setting	Activity
Any transmission scenario	Health worker or caregiver	Health care facility (including primary, secondary, tertiary care levels, outpatient care, and LTCF)	When in contact with suspect or confirmed COVID-19 patient
		Home care	When in close contact or when a distance of at least 1 m cannot be maintained from a suspect or confirmed COVID-19 patient

For the **general public**, the World Health Organization recommends the use of a medical face mask for the following situations/settings and populations as a means of source control and/or wearer protection:

Table 2 - World Health Organization: Medical Face Mask Guidance for Use by the General Public [5]

Situations/settings	Population
Settings where physical distancing cannot be achieved and increased risk of infection and/or negative outcomes	Vulnerable populations: • People aged ≥60 years • People with underlying comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease, immunosuppression
Any setting in the community (any transmission scenario)	Persons with any symptoms suggestive of COVID-19

The World Health Organization also cautions that "the use of medical masks in the community may divert this critical resource from the health workers and others who need them the most. In settings where medical masks are in short supply, medical masks should be reserved for health workers and at-risk individuals when indicated [5]."

Respirator

A filtering facepiece respirator (FFR), or respirator, is similar to a medical face mask in that it must offer a balance of filtration and breathability [5]. A key difference between a medical face mask and a respirator is in its required filtration capabilities. Whereas a medical face mask is designed to filter **3 µm** droplets, a respirator must be designed to filter **0.075 µm** solid particles [5]. In addition, respirators must be able to filter at least 94% of solid NaCl particles and oil droplets (when tested to EN 149, FFP2) or filter at least 95% of NaCl particles (when tested to NIOSH 42 CFR part 84, N95 FFR). To achieve such stringent requirements, the respirator must also ensure a tight seal around the wearer's face [5].

Figure 2 - Example Respirator/FFR
(https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Health-Care-Particulate-Respirator-and-Surgical-Mask-1860-N95-120-EA-Case/?N=5002385+8707795+8707798+8710839+8711100+3294795990&rt=rud)

For **health workers or caregivers**, the World Health Organization recommends the use of a respirator for the following transmission scenarios, settings, and activities:

Table 3 - World Health Organization: Respirator Guidance for Use by Health Workers or Caregivers [5]

Transmission scenario	Who	Setting	Activity
Any transmission scenario	Health worker	Health care facility (including long-term care facility), in settings where aerosol generating procedures (AGP) are performed	Performing an AGP on a suspected or confirmed COVID-19 patient or providing care in a setting where AGPs are in place for COVID-19 patients.

The World Health Organization does not recommend the use of a respirator for the general public [5].

Performance Levels of Medical Face Masks

There are two different standards that define requirements and test methods for medical face masks: European standard BS EN 14683:2019 and American standard ASTM F2100-19. Both standards apply to medical face masks that are intended to limit the transmission of infection from medical staff to patients (source control). Additionally, medical face masks may be designed with some degree of protection to guard against splashes of potentially contaminated liquids [8]. Medical face masks are generally used during surgical procedures and other medical settings with similar requirements, but they may also be used during epidemic or pandemic situations to help reduce the spread of infection [8].

It is not necessary for a medical face mask to be compliant with *both* EN 14683:2019 and ASTM F2100-19; compliance with one or the other is sufficient. However, it is important to consult with the Ministry of Health (or other appropriate authority) when deciding which standard to follow.

BS EN 14683:2019

The medical face mask performance levels of this standard are defined as type I, II, and IIR. The BS EN 14683:2019 requirements for the medical mask by type are summarized in Table 4 below:

Table 4 - BS EN 14683:2019 Medical Mask Types [8]

Characteristic	Type I	Type II	Type IIR
Bacterial filtration efficiency (BFE)	≥ 95%	≥ 98%	≥ 98%
Differential pressure	< 4.08 mm H_2O/cm^2 (< 40 Pa/cm^2)	< 4.08 mm H_2O/cm^2 (< 40 Pa/cm^2)	< 6.12 mm H_2O/cm^2 (< 60 Pa/cm^2)
Splash resistance	Not required	Not required	≥16.0 kPa
Microbial cleanliness	≤30 cfu/g	≤30 cfu/g	≤30 cfu/g

EN 14683:2019 advises that "Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations [8]." The World Health Organization recommends the use of Type I masks for patients and Type II or IIR masks for healthcare workers [4].

ASTM F2100-19

The medical face mask performance levels of this standard, defined as levels 1 through 3, are based on the barrier performance properties of the mask materials; barrier performance is further characterized by fluid resistance, bacterial filtration efficiency, and sub-micron filtration efficiency [7]. The ASTM F2100-19 requirements for the medical mask by performance level are summarized in Table 5 below:

Table 5 – ASTM F2100-19 Medical Mask Performance Levels [7]

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial filtration efficiency (BFE)	≥ 95%	≥ 98%	≥ 98%
Differential pressure	< 5.0 mm H_2O/cm^2	< 6.0 mm H_2O/cm^2	< 6.0 mm H_2O/cm^2
Sub-micron particulate filtration efficiency at 0.1 micron	≥ 95%	≥ 98%	≥ 98%
Resistance to penetration by synthetic blood	≥ 80 mmHg	≥ 120 mmHg	≥ 160 mmHg
Flame spread	Class I	Class I	Class I

The World Health Organization recommends the use of at least Level 1 Barrier Type I masks patients and healthcare workers [4].

Selection Guidance

In general, the selection of the medical mask performance level should be guided by the potential exposure hazards associated with the intended use situation. For example [7]:

- General-use masks (minimal fluid resistance) may be suitable for isolation settings and certain types of patient care
- Sub-micron filtering masks may be appropriate for procedures involving the generation of sub-micron particles, such as in laser or electrocautery surgery
- Fluid-resistant masks may be necessary for procedures involving the likely exposure to blood or bodily fluids

Typically, increasing the barrier performance of a surgical mask results in a reduction of breathability [7]; this tradeoff is an important consideration to factor into procurement and design decisions.

Technical Design and Test Criteria

This section provides a concise introduction to the key design features of medical face masks, including a brief explanation of why each feature is important and how it is tested (as applicable). Collectively, this set of technical features and test criteria are what ensure the safety and effectiveness of medical face masks.

General Construction

The construction of the medical face mask can be highly variable from one design to the next. The key aspects of the general construction to consider include the following:

Identification of Outer Layer vs. Inner Layer

To reduce the likelihood of inadvertent contamination (e.g. if the wearer momentarily takes the mask off, then puts it back on), it is important for the wearer to be able to distinguish between the outer layer and the inner layer of the mask. One way to accomplish this is to designate the outer and inner layer to be a different color. It is strongly encouraged to utilize a design that does not have an identical and indistinguishable outer surface and inner surface.

Test method: Verify by visual inspection that it is possible to identify the outer surface and inner surface of the non-medical face mask.

Seam Placement

Seams are inherently weak points for maintaining the integrity of a material's filtration efficiency. Therefore, it is not recommended to have a seam near the center of the face mask (vertically or horizontally).

Test method: Verify by visual inspection that a seam is not located near the center of the face mask.

Durability

The mask materials as well as the overall construction of it must be able to withstand the handling and wear throughout the expected lifetime of the mask [9].

Test method: Qualitatively evaluate the mask's durability by donning and doffing the non-medical face mask at least 5 times [9].

Coverage and Fit

It is important for the mask to be able to appropriately cover the wearer's nose and mouth while comfortably securing to the ears or head.

Sizing

Anthropometric data, such as what may be found in ISO/TS 16976-2:2015 *Respiratory protective devices – Human factors – Part 2: Anthropometrics*, may be used to help determine the most appropriate sizing to fit the general population. It may be desirable to have one-size-fits-most for adults and a separate one-size-fits-most for children.

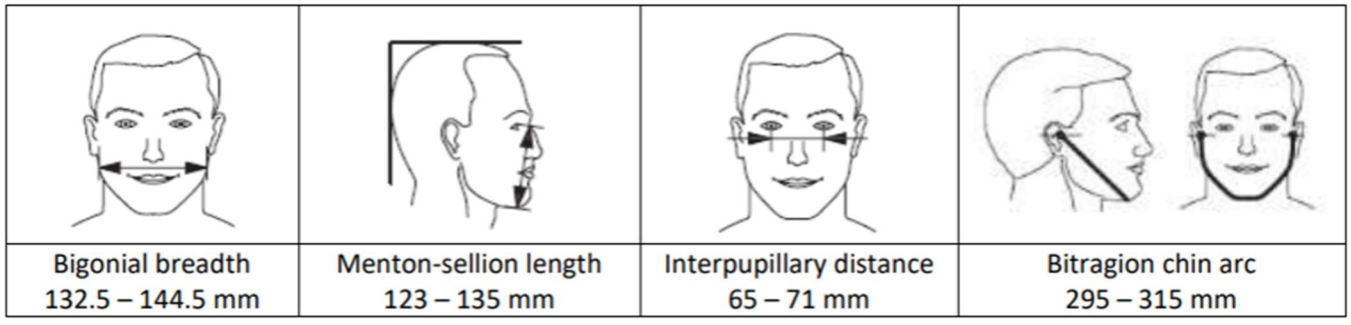

Figure 3 - Anthropometric data from ISO/TS 16976:2015 [9]

Test method: Qualitatively evaluate the mask's fit and coverage on wearers of various face sizes and proportions.

Ties vs. Ear Loops
Whether a mask is provided with ear loops or ties is primarily a matter of preference. Ear loops are well suited for easy donning and doffing, while ties may be more comfortable for prolonged use (as the ear loops may irritate the ears).

Test method: Qualitatively evaluate the mask's securing mechanism (ties or ear loops) and coverage on wearers of various face sizes and proportions. Ensure that the mask may be secured with sufficient ease, the mask stays in place during foreseeable use, and that it may be worn without excessive tightness and discomfort [9].

Nose Clamp
Some medical mask designs provide a nose clamp that can be shaped to the contours of the wearer's nose. This may help to provide a better seal as well as reduce the tendency to fog up eyewear.

Test method: Qualitatively evaluate the mask's nose clamp on wearers of various face sizes and proportions. Ensure that the mask may be shaped to the contours of the wearer's nose without causing discomfort.

Bacterial Filtration Efficiency
Required for ASTM F2100-19 and EN 14683:2019

ASTM F2100-19
ASTM F2100-19 defines bacterial filtration efficiency (BFE) as "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 [7]."

Test method: Determine the bacterial filtration efficiency as directed in ASTM F2101-19, *Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials Using a Biological Aerosol of Staphylococcus aureus* [10].

Acceptance criteria: Refer to the Table 5 value for the corresponding mask level barrier.

EN 14683:2019
EN 14683:2019 defines bacterial filtration efficiency as the "efficiency of the medical face mask material(s) as a barrier to bacterial penetration [8]."

Test method: Determine the bacterial filtration efficiency as directed in EN 14683:2019, *Medical Face Masks – Requirements and Tests*, Annex B [7].

Acceptance criteria: Refer to the Table 4 value for the corresponding mask type.

Breathability (Differential Pressure)
Required for ASTM F2100-19 and EN 14683:2019
The differential pressure (pressure drop) across the medical face mask material should be assessed to ensure it allows adequate breathability. When considering a candidate material, a qualitative breathability evaluation (go / no go) may aid in the selection/screening process. However, a more quantitative analysis of breathability, including tests of the pressure drop across the mask and CO2 accumulation, is an important requirement to consider to ensure adequate usability (which will therefore influence compliance) [11].

ASTM F2100-19
Test method: Determine breathing resistance (differential pressure) as directed in EN 14683:2019, *Medical Face Masks – Requirements and Tests*, Annex C [8].

Acceptance criteria: Refer to the Table 5 value for the corresponding mask level barrier.

EN 14683:2019

Test method: Determine breathing resistance (differential pressure) as directed in EN 14683:2019, *Medical Face Masks – Requirements and Tests*, Annex C [8].

Acceptance criteria: Refer to the Table 4 value for the corresponding mask type.

MakerMask.org

Test method (approximation): Perform the DIY Mask Test for Breathability provided at https://makermask.org/diy-mask-tests/. This test assesses the breathability of mask materials by measuring how far an individual can blow a small object (high breathability = longest distances) [12].

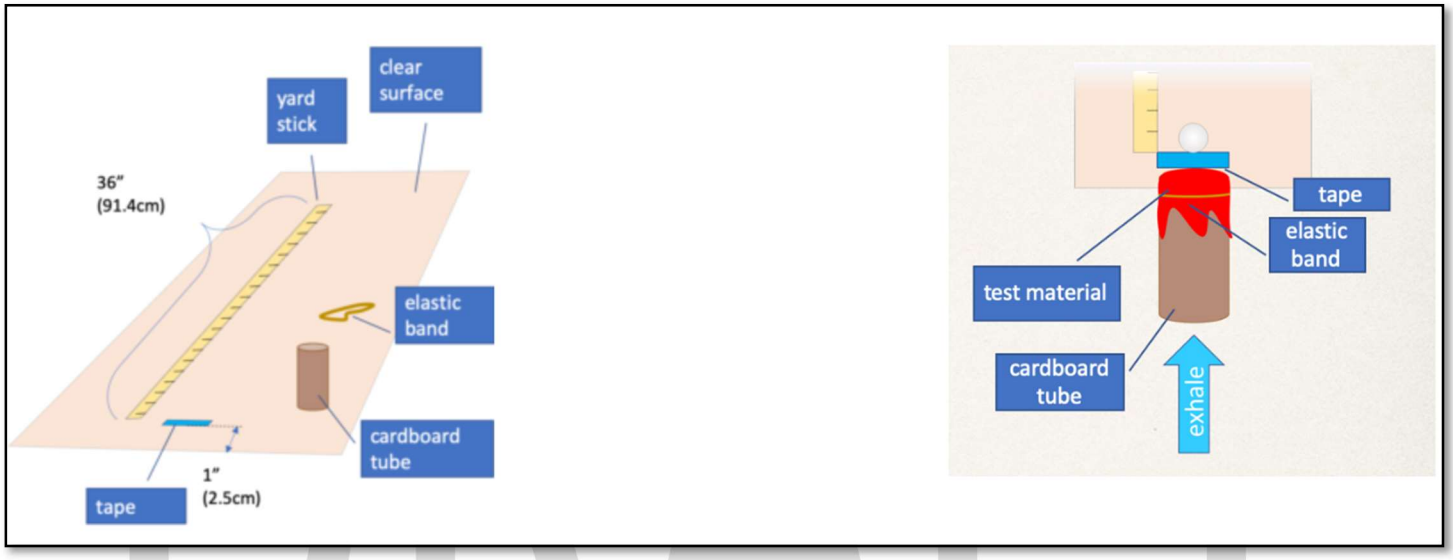

Figure 4 - Overview of MakerMask.org Breathability Test [12]

Sub-Micron Particulate Filtration Efficiency

Required for ASTM F2100-19 only

ASTM F2100-19

ASTM F2100-19 defines sub-micron particulate filtration efficiency as "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 [7]."

Test method: Determine the particulate filtration efficiency as directed in ASTM F2299/F2299M-03, *Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres* [13].

MakerMask.org

Test method (approximation): Perform the DIY Mask Test for Filtration provided at https://makermask.org/diy-mask-tests/. This test may be used to determine how well a material can keep particles (< 50 µm) from crossing from one side of the mask/material to the other [12].

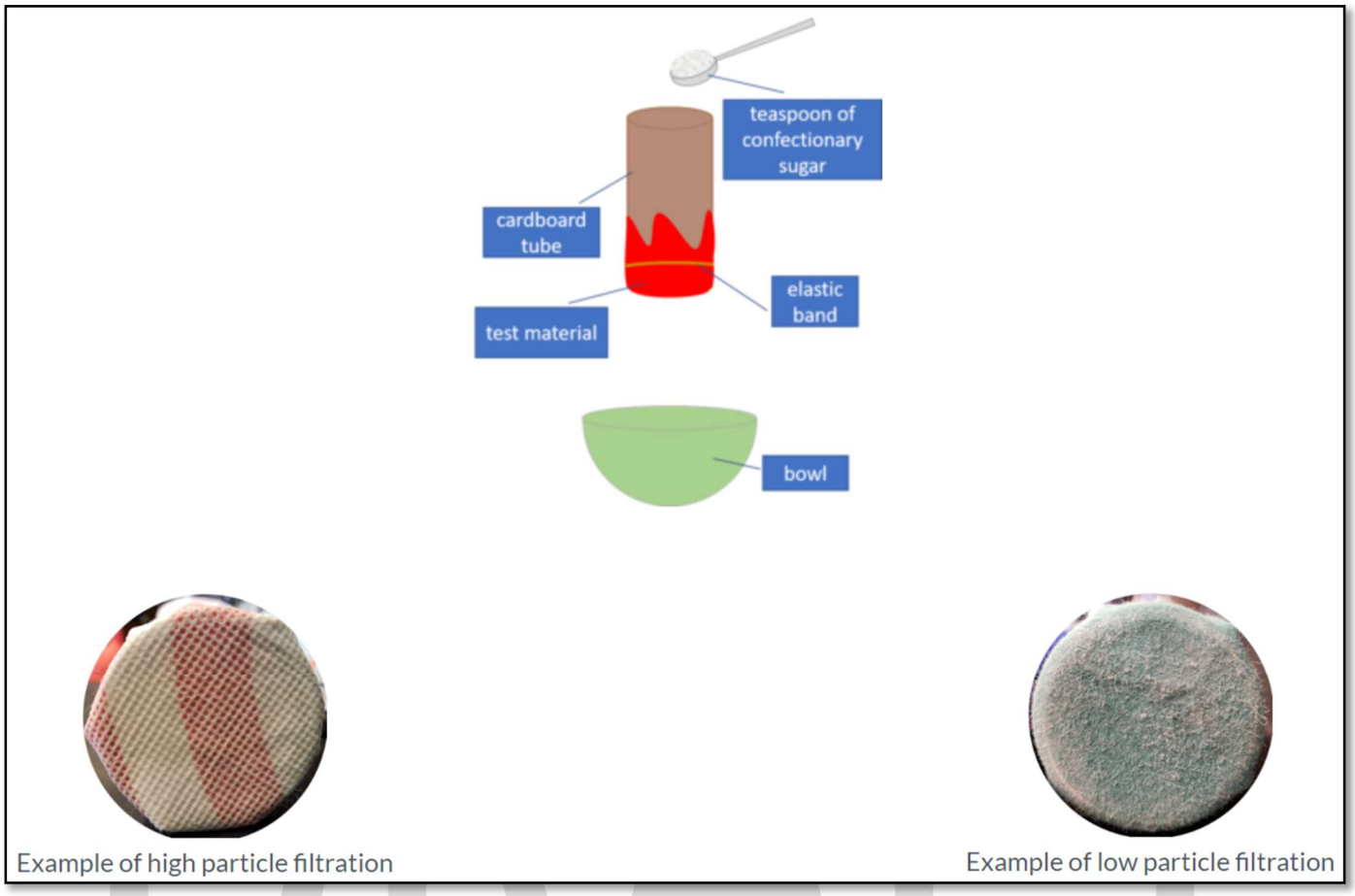

Figure 5 - Overview of MakerMask.org Filtration Test [12]

Resistance to Penetration by Synthetic Blood / Splash Resistance

Required for ASTM F2100-19 and EN 14683:2019 Type IIR masks

Healthcare workers involved in caring for patients can be exposed to biological liquids capable of transmitting disease. Even though engineering controls cannot mitigate all possible exposures, it is possible to reduce the likelihood of direct skin and mucous membrane contact through the use of PPE that resists penetration [14].

A lack of fluid resistance of the face mask material may be mitigated (if necessary) with the use of a face shield in conjunction with the face mask.

ASTM F2100-19

Test method: Determine the synthetic blood penetration resistance as specified in ASTM F1862/F1862M-17, *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)* [14].

Acceptance criteria: Refer to the Table 5 value for the corresponding mask level barrier.

EN 14683:2019

Test method: Determine splash resistance as directed in ISO 22609:2004, *Clothing for protection against infectious agents – Medical face masks – Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)* [15].

Acceptance criteria: Refer to the Table 4 value for the Type IIR mask type.

MakerMask.org

Test method (approximation): Perform the DIY Mask Test for Water Resistance provided at https://makermask.org/diy-mask-tests/. This test assesses how well a material can keep water from crossing from one side of the mask/material to the other [12].

Figure 6 - Overview of MakerMask.org Water Resistance Test [12]

Microbial Cleanliness (Bioburden)

Required for EN 14683:2019 only

EN 14683:2019

EN 14683:2019 defines bacterial filtration efficiency as the "efficiency of the medical face mask material(s) as a barrier to bacterial penetration [8]."

Test method: Determine the microbial cleanliness as directed in ISO 11737-1:2018, *Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products* [16].

Acceptance criteria: Refer to the Table 4 value for the corresponding mask type.

Flame-Resistance (Flame Spread)

Required for ASTM F2100-19 only

Materials used in the construction of surgical masks must meet the requirements for Class I, normal flammability, as specified in 16 CFR part 1610 [7].

ASTM F2100-19

Test method: Test the Class 1 flammability per 16 CFR 1610, *Standard for the Flammability of Clothing Textiles.*

Biocompatibility

*Required for EN 14683:2019 only**

Medical face masks may be in contact with intact skin for a duration of ≤24 hours. To ensure biocompatibility, the skin-contacting band material needs to be evaluated for potential adverse reactions. Biocompatibility tests for cytotoxicity, sensitization, and irritation or intracutaneous reactivity are described below.

*Note: Although biocompatibility is not a requirement of ASTM F2100-19, it is a requirement of US FDA regulation 21 CFR 878.4040 [2].

Cytotoxicity

Cytotoxicity is the quality of being toxic to cells. Cytotoxicity test methods are designed to evaluate the acute adverse biological effects of extractables from materials; cells exposed to test or control materials are observed for visible signs of toxicity (such as a change in the size or appearance of cellular components or a disruption in their configuration) [17].

Test method: ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity* [18].

Sensitization

Sensitization or hypersensitivity reactions may occur in response to repeated or prolonged exposure to a chemical substance [19].

Test method: ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization* [20].

Irritation or Intracutaneous Reactivity

The chemicals leached from materials may produce skin irritation, which is a tissue response characterized by inflammation, redness, swelling, and sometimes accompanied by heat and pain [21].

Test method: ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization* [20].

Natural Rubber Latex

Due to reports of allergic reactions, some medical device manufacturers started labeling products as "latex-free," "does not contain natural rubber latex," or "does not contain latex." However, it is not possible to reliably assure the complete absence of the allergens associated with the reactions to natural rubber latex. Therefore, the U.S. FDA advises manufacturers who want to indicate that natural rubber latex was not used in the manufacturing of their product to "inform users that a product, product container, or product packaging was not made with natural rubber latex [22]."

Regulatory Assessment

Intended use

Surgical face masks are personal protective equipment (PPE) that are used to protect the wearer from airborne particles and from liquids that may contaminate the face. They are a relatively loose-fitting mask that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the surrounding environment. Although a surgical mask is meant to help block large droplets, splashes, sprays, or splatter (that may contain viruses and bacteria), they are not designed to block very small airborne particles [6].

Compliance with U.S. FDA Regulatory Requirements

Surgical face masks are categorized under the LXX (mask, surgical) FDA product code (Figure 7) and are subject to the regulations defined by 21 CFR part 878.4040 (Figure 8).

Device	Mask, Surgical
Regulation Description	Surgical apparel.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General Hospital
Product Code	FXX
Premarket Review	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(k)
Regulation Number	878.4040
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Recognized Consensus Standards

- 6-254 ASTM F2100-11 (Reapproved 2018)
  Standard Specification for Performance of Materials Used in Medical Face Masks
- 6-335 ASTM F2101-14
  Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- 6-406 ASTM F1862/F1862M-17
  Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- 6-425 ASTM F2100-19
  Standard Specification for Performance of Materials Used in Medical Face Masks
- 6-427 ASTM F2101-19
  Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

Implanted Device?	No
Life-Sustain/Support Device?	No

Third Party Review

- Eligible for *Accredited Persons Program*

Accredited Persons

- Accelerated Device Approval Services, Llc
- Biomarkers And Diagnostics Consulting, Llc
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc

Figure 7 - FDA Product Code FXX [1]

878.4040 Surgical apparel.

§ 878.4040 Surgical apparel.

(a) *Identification.* Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

(b) *Classification.* (1) Class II (special controls) for surgical gowns and surgical masks. A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9, and the following conditions for exemption:

(i) The user contacting components of the device must be demonstrated to be biocompatible.

(ii) Analysis and nonclinical testing must:

(A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use; and

(B) Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device.

(iii) NIOSH approved under its regulation.

(2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2317, Jan. 14, 2000; 83 FR 22848, May 17, 2018]

Figure 8 - Regulation 21 CFR 878.4040 [2]

FDA recognized consensus standards defined for the LXX product code (Figure 7) are identified in Table 6. Each recognized consensus standard is cross-referenced with the corresponding section of this guidance document.

Table 6 – FDA Recognized Consensus Standards for Medical Face Masks

Recognized Consensus Standard	Reference
ASTM F2100-11 (Reapproved 2018), *Standard Specification for Performance of Materials Used in Medical Face Masks* or ASTM F2100-19, *Standard Specification for Performance of Materials Used in Medical Face Masks*	Performance Levels of Medical Face Masks (page 4); this standard includes the following requirements: • **Bacterial Filtration Efficiency**: described on page 7 and captured in Table 10 • **Breathability (Differential Pressure)**: described on page 7 and captured in Table 10 • **Sub-Micron Particulate Filtration Efficiency**: described on page 8 and captured in Table 10 • **Resistance to Penetration by Synthetic Blood / Splash Resistance**: described on page 9 and captured in Table 10 • **Flammability**: described on page 10 and captured in Table 10
ASTM F2101-14, *Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus* or ASTM F2101-19, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus	**Bacterial Filtration Efficiency**: described on page 7 and captured in Table 10
ASTM F1862/F1862M-17, *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*	**Resistance to Penetration by Synthetic Blood / Splash Resistance**: described on page 9 and captured in Table 10

Compliance with EU Regulatory Requirements: 2016/425 on PPE

This section considers the *Essential Health and Safety Requirements* set forth in Annex II of 2016/425 on PPE [3]. The Preliminary Remarks (Figure 9) outline the high level expectations and responsibilities of the regulations.

PRELIMINARY REMARKS

1. The essential health and safety requirements laid down in this Regulation are compulsory.

2. Obligations related to essential health and safety requirements apply only where the corresponding risk exists for the PPE in question.

3. The essential health and safety requirements are to be interpreted and applied in such a way as to take into account the state of the art and current practice at the time of design and manufacture, as well as technical and economic considerations which are consistent with a high degree of health and safety protection.

4. The manufacturer shall carry out a risk assessment in order to identify the risks which apply to his PPE. He shall then design and manufacture it taking into account that assessment.

5. When designing and manufacturing the PPE, and when drafting the instructions, the manufacturer shall envisage not only the intended use of the PPE, but also the reasonably foreseeable uses. Where applicable, the health and safety of persons other than the user shall be ensured.

Figure 9 - Preliminary Remarks, Annex II

The requirements of section 1, *General Requirements Applicable to All PPE*, are captured and evaluated in Table 7.

Table 7 - Annex II, General Requirements Applicable to All PPE [3]

Section 1 Requirement	Applicability to Face Shields
1.1. Design principles	
1.1.1. Ergonomics PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.	Applicable; addressed by the **Coverage and Fit**, **Flame-Resistance**, and **Biocompatibility** criteria in Table 10.
1.1.2. Levels and classes of protection **1.1.2.1. Optimum level of protection** The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.	Applicable; addressed by **Bacterial Filtration Efficiency**, **Differential Pressure**, **Sub-Micron Particulate Filtration Efficiency**, **Resistance to Penetration by Synthetic Blood / Splash Resistance**, **Microbial Cleanliness** criteria in Table 10.
1.1.2.2. Classes of protection appropriate to different levels of risk Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.	Applicable; addressed by **Bacterial Filtration Efficiency**, **Differential Pressure**, **Sub-Micron Particulate Filtration Efficiency**, **Resistance to Penetration by Synthetic Blood / Splash Resistance**, **Microbial Cleanliness** criteria in Table 10. Refer to Table 5 for the levels of protection for ASTM F2100-19 medical face masks.

Section 1 Requirement	Applicability to Face Shields
	Refer to Table 4 for the levels of protection for EN 14683:2019 medical face masks.
1.2. Innocuousness of PPE	
1.2.1. Absence of inherent risks and other nuisance factors PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.	Applicable; addressed by the **Coverage and Fit**, **Flame-Resistance**, and **Biocompatibility** criteria in Table 10.
1.2.1.1. Suitable constituent materials The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.	Applicable; addressed by the **Biocompatibility** criterion in Table 10.
1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.	Applicable; addressed by the **Coverage and Fit** criterion in Table 10.
1.2.1.3. Maximum permissible user impediment Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.	Not applicable; medical face masks do not adversely impair sensory perceptions.
1.3. Comfort and effectiveness	
1.3.1. Adaptation of PPE to user morphology PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.	Applicable; addressed by the **Coverage and Fit** criterion in Table 10.
1.3.2. Lightness and strength PPE must be as light as possible without prejudicing its strength and effectiveness. PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.	Not applicable; the effectiveness of medical face masks are not linked to a tradeoff between weight and strength.
1.3.3. Compatibility of different types of PPE intended for simultaneous use If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.	Not applicable
1.3.4. Protective clothing containing removable protectors Protective clothing containing removable protectors constitutes PPE and shall be assessed as a combination during conformity assessment procedures.	Not applicable
1.4. Manufacturer's instructions and information	
In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:	Applicable; addressed by the **Manufacturer Info** criterion in Table 10.

Section 1 Requirement	Applicability to Face Shields
(a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;	Applicable; addressed by the **Cleaning and Disinfection** criterion in Table 10.
(b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;	Applicable; addressed by the **Performance Level** criterion in Table 10.
(c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;	Not applicable – there are no accessories to medical face masks.
(d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;	Applicable; addressed by the **Performance Level** criterion in Table 10.
(e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;	Not applicable – medical face masks do not have an expiration date.
(f) where applicable, the type of packaging suitable for transport;	Not applicable – medical face masks do not have any components sensitive to temperature or vibration.
(g) the significance of any markings (see point 2.12);	Not applicable – no markings/symbols are required.
(h) the risk against which the PPE is designed to protect;	Applicable; addressed by the **Instructions for Use – General** criterion in Table 10.
(i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;	Not applicable – formal EU approval is not being pursued
(j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;	Not applicable – formal EU approval is not being pursued
(k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;	Applicable; addressed by the **Instructions for Use – General** criterion in Table 10.
(l) the internet address where the EU declaration of conformity can be accessed.	Not applicable – formal EU approval is not being pursued
The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.	Not applicable – formal EU approval is not being pursued

The requirements of section 2, *Additional Requirements Common to Several Types of PPE*, are captured and evaluated Table 8.

Table 8 - Annex II, Additional Requirements Common to Several Types of PPE [3]

Section 2 Requirement	Applicability to Face Shields
2.1. PPE incorporating adjustment systems If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.	Applicable; addressed by the **Coverage and Fit** criterion in Table 10.
2.2. PPE enclosing the parts of the body to be protected PPE must be designed and manufactured in a way that perspiration resulting from use is minimised. Otherwise it must be equipped with means of absorbing perspiration.	Not applicable; the medical face mask provides coverage of the nose and mouth without fully enclosing the face or head.
2.3. PPE for the face, eyes and respiratory system Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.	Applicable; addressed by the **Breathability** criterion in Table 10.

Section 2 Requirement	Applicability to Face Shields
The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user. If necessary, such PPE must be treated or provided with means to prevent misting-up. Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.	
2.4. PPE subject to ageing If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging. If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance. Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.	Not applicable – medical face masks do not have an expiration date.
2.5. PPE which may be caught up during use Where the foreseeable conditions of use include, in particular, the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must be designed and manufactured in such a way that a constituent part will break or tear, thereby eliminating the danger.	Not applicable; foreseeable hazardous condition does not exist.
2.6. PPE for use in potentially explosive atmospheres PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.	Not applicable; medical face masks are intended for use in the healthcare environment and not potentially explosive atmospheres.
2.7. PPE intended for rapid intervention or to be put on or removed rapidly Those types of PPE must be designed and manufactured in such a way as to minimise the time required for putting on and removing the equipment. Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate such systems quickly and easily.	Applicable; addressed by the **Coverage and Fit** criterion in Table 10.
2.8. PPE for intervention in very dangerous situations The instructions supplied by the manufacturer with PPE for	Not applicable

Section 2 Requirement	Applicability to Face Shields
intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user. The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user. Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.	
2.9. PPE incorporating components which can be adjusted or removed by the user Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.	Applicable; addressed by the **Coverage and Fit** criterion in Table 10.
2.10. PPE for connection to complementary equipment external to the PPE Where PPE incorporates a connexion system permitting its connection to other complementary equipment, the means of attachment must be designed and manufactured in such a way as to enable it to be mounted only on appropriate equipment.	Not applicable; no connection is provided to complementary equipment.
2.11. PPE incorporating a fluid circulation system Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed in such a way as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.	Not applicable; medical face masks do not incorporate a fluid circulation system.
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market. Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.	Not applicable – no markings/symbols are required.
2.13. PPE capable of signalling the user's presence visually PPE intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.	Not applicable; medical face masks are not intended to visually indicate the user's presence.

Section 2 Requirement	Applicability to Face Shields
2.14. Multi-risk PPE PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured in such a way as to satisfy, in particular, the essential health and safety requirements specific to each of those risks.	Not applicable; medical face masks are intended to protect the wearer from airborne particles and (optionally) from liquids that may contaminate the face.

The requirements of section 3, Additional Requirements Specific to Particular Risks, are captured and evaluated Table 9.

Table 9 - Annex II, Additional Requirements Specific to Particular Risks [3]

Section 3 Requirement	Applicability to Face Shields
3.1. Protection against mechanical impact	Not applicable
3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle	Not applicable
3.1.2. Falls	Not applicable
3.1.3. Mechanical vibration	Not applicable
3.2. Protection against static compression of a part of the body	Not applicable
3.3. Protection against mechanical injuries	Not applicable
3.4. Protection in liquids	Not applicable
3.4.1. Protection of drowning	Not applicable
3.4.2. Buoyancy aids	Not applicable
3.5. Protection against the harmful effects of noise	Not applicable
3.6. Protection against heat and/or fire	Not applicable
3.6.1. PPE constituent materials and other components	Not applicable
3.6.2. Complete PPE ready for use	Not applicable
3.7. Protection against cold	Not applicable
3.7.1. PPE constituent materials and other components	Not applicable
3.7.2. Complete PPE ready for use	Not applicable
3.8. Protection against electric shock	Not applicable
3.8.1. Insulating equipment	Not applicable
3.8.2. Conductive equipment	Not applicable
3.9. Radiation protection	Not applicable
3.9.1. Non-ionising radiation	Not applicable
3.9.2. Ionising radiation	Not applicable
3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents	Applicable
3.10.1. Respiratory protection PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration. The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source. The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.	Not applicable; medical face masks are not intended for the protection of the respiratory system. They are a relatively loose-fitting mask that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the surrounding environment. Although a medical face mask is meant to help block large droplets, splashes, sprays, or splatter (that may contain viruses and bacteria), they are not designed to block very small airborne particles [6].

Section 3 Requirement	Applicability to Face Shields
The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user. The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly. In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.	
3.10.2. Protection against cutaneous and ocular contact PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended. To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear. Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.	Applicable; addressed by **Bacterial Filtration Efficiency**, **Differential Pressure**, **Sub-Micron Particulate Filtration Efficiency**, **Resistance to Penetration by Synthetic Blood / Splash Resistance**, **Microbial Cleanliness** criteria in Table 10.
3.11. Diving equipment	Not applicable

Recommended Safety and Effectiveness Criteria

Leveraging the established requirements and key inputs of:

- US FDA 21 CFR 878.4040 [2],
- US FDA recognized consensus standards for product code FXX [1],
- EU 2016/425 on PPE [3],
- BS EN 14683:2019 [8],
- ASTM F2109-19 [7]
- as well as the WHO guidance on PPE for COVID-19 [4]

the following checklist has been developed to specify a set of recommended essential criteria that may be used to assess adequate safety and effectiveness of a candidate medical face mask design. The objective of this checklist is to provide sufficient confidence that the known and potential benefits outweigh the known and potential risks of medical face masks for use as PPE; likewise, the known and potential benefits of medical face masks for use as PPE outweigh the total lack of medical face masks available for use as PPE.

During the evaluation of a candidate medical face mask design, Table 10 shall be completed to capture the corresponding evidence and justification for how each criterion is satisfied.

Table 10 - Essential Criteria to Assure Safety and Effectiveness of Medical Face Masks

Criterion [Source]	**Description**	**Evidence** *[example rationale or references]*
PPE design requirements		
Bacterial Filtration Efficiency ASTM F2100-19 clauses 6.1 and 9.1 [7] EN 14683:2019 clause 5.2.2 [8] Also refer to 1.1.2.1, 1.1.2.2, 3.10.2 of EU 2016/425 on PPE [3]	If tested to ASTM F2100-19, the medical face mask meets the requirements as specified in Table 5 for the corresponding mask level barrier. If tested to EN 14683:2019, the medical face mask meets the requirements as specified in Table 4 for the corresponding mask type.	*[Include a reference to the test results that demonstrate the appropriate bacterial filtration efficiency]*
Differential Pressure (Breathability) ASTM F2100-19 clauses 6.1 and 9.2 [7] EN 14683:2019 clause 5.2.3 [8] Also refer to 1.1.2.1, 1.1.2.2, 2.3, 3.10.2 of EU 2016/425 on PPE [3]	If tested to ASTM F2100-19, the medical face mask meets the requirements as specified in Table 5 for the corresponding mask level barrier. If tested to EN 14683:2019, the medical face mask meets the requirements as specified in Table 4 for the corresponding mask type.	*[Include a reference to the test results that demonstrate the appropriate differential pressure (breathability)]*
Sub-Micron Particulate Filtration Efficiency ASTM F2100-19 clauses 6.1 and 9.3 [7]	Only required if tested to ASTM F2100-19; the medical face mask meets the requirements as	*[If tested to ASTM F2100-19, include a reference to the test results that*

Criterion [Source]	**Description**	**Evidence** *[example rationale or references]*
Also refer to 1.1.2.1, 1.1.2.2, 3.10.2 of EU 2016/425 on PPE [3]	specified in Table 5 for the corresponding mask level barrier.	*demonstrate the appropriate sub-micron particulate filtration efficiency]* *[If tested to EN 14683:2019, this row is N/A]*
Resistance to Penetration by Synthetic Blood / Splash Resistance ASTM F2100-19 clauses 6.1 and 9.4 [7] EN 14683:2019 clause 5.2.4 [8] 21 CFR 878.4040 [2]: (B) Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device. Also refer to 1.1.2.1, 1.1.2.2, 3.10.2 of EU 2016/425 on PPE [3]	If tested to ASTM F2100-19, the medical face mask meets the requirements as specified in Table 5 for the corresponding mask level barrier. If tested to EN 14683:2019, the medical face mask meets the requirements as specified in Table 4 for the corresponding mask type.	*[Include a reference to the test results that demonstrate the appropriate resistance to penetration by synthetic blood / splash resistance. Note: EN 14683:2019 Type I and Type II masks do not require splash resistance.]*
Microbial Cleanliness (Bioburden) EN 14683:2019 clause 5.2.5 [8] Also refer to 1.1.2.1, 1.1.2.2, 3.10.2 of EU 2016/425 on PPE [3]	Only required if tested to EN 14683:2019; the medical face mask meets the requirements as specified in Table 4 for the corresponding mask type.	*[If tested to EN 14683:2019, include a reference to the test results that demonstrate the appropriate microbial cleanliness (bioburden)]* *[If tested to ASTM F2100-19, this row is N/A]*
Biocompatibility EN 14683:2019 clause 5.2.6 [8] 21 CFR 878.4040 [2]: (i) The user contacting components of the device must be demonstrated to be biocompatible. Also refer to 1.1.1, 1.2.1, 1.2.1.1 of EU 2016/425 on PPE [3]	The medical face mask may be in contact with intact skin for a duration of ≤24 hours. To ensure biocompatibility, the skin-contacting material needs to be evaluated for potential adverse reactions. The product, product container, or product packaging should not be made with natural rubber latex.	*[The product labeling (e.g. instructions for use) includes a list of the body-contacting materials.]* *[Rationale to support that the skin-contacting material is not constructed from a known allergen.]* *[The product, product container, and product packaging are not made with natural rubber latex.]*

Criterion [Source]	**Description**	**Evidence** *[example rationale or references]*
		[ISO 10993-5:2009 and ISO 10993-10:2010 test reports or material datasheet indicating compliance to these standards.]
Flame-Resistance (Flame Spread) ASTM F2100-19 clauses 6.2 and 9.5 [7] 21 CFR 878.4040 [2]: (A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use. Also refer to 1.1.1, and 1.2.1 of EU 2016/425 on PPE [3]	The medical face mask should meet at least one of the following requirements: • The medical face mask does not contain any materials that will cause flammability • The medical face mask meets Class I or Class II flammability requirements per 16 CFR 1610 (or equivalent) • The medical face mask is labeled with a recommendation against use in the presence of high intensity heat source or flammable gas	*[The medical face mask does not contain any materials that will cause flammability.]* *[The medical face mask meets Class I flammability requirements per 16 CFR 1610 or equivalent (and include reference to test report).]* *[The medical face mask is labeled with a recommendation against use in the presence of high intensity heat source or flammable gas.]*
Coverage and Fit Refer to 1.1.1, 1.2.1, 1.2.1.2, 1.3.1, 2.1, 2.7, 2.9 of EU 2016/425 on PPE [3]	The medical face mask provides adequate coverage of the nose and mouth (considering the range of face dimensions of potential wearers) and ensures a secure but comfortable fit to keep the mask in place. The face shield shall be simple to put on and to take off. The medical face mask shall be free from rough surfaces, sharp edges, sharp points or other defects which are likely to cause discomfort or injury during use.	*[Include a reference to the dimensional drawing of the medical face mask]* *[Summarize how the coverage and fit adequacy was assessed (e.g. evaluated with healthcare workers)]* *[The medical face mask does not have projections, sharp edges, or other defects which are likely to cause discomfort or injury during use.]*
PPE labeling (includes instructions for use) requirements		
Instructions for Use – General Instructions for use shall minimally contain the following information: • (h) Intended use; the risk against which the PPE is designed to protect • (k) References to the relevant harmonized standard(s) used, including the date of the	The PPE shall include instructions for use that are easily understandable and provide the required information.	*[Include a reference to the product labeling / instructions for use]*

Criterion [Source]	**Description**	**Evidence** *[example rationale or references]*
standard(s), or references to the other technical specifications used Refer to 1.4 of EU 2016/425 on PPE [3]		
Performance Level (b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE; (d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use; Refer to 1.4 of EU 2016/425 on PPE [3]	The PPE or its associated instructions for use shall include the actual tested/measured values to support the requirements established in Table 5 (ASTM F2100-19) / Table 4 (EN 14683:2019). The achieved level (Barrier Level or Type) shall also be specified.	*[Include a reference to the product labeling / instructions for use]*
Manufacturer Info (17) When placing PPE on the market, every importer should indicate on the PPE his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the PPE does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the PPE. Refer to 1.4 of EU 2016/425 on PPE [3]	The PPE or its associated instructions for use shall include the manufacturer's name and contact information.	*[Include a reference to the product labeling / instructions for use]*
Cleaning and Disinfection (a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions; Refer to 1.4 of EU 2016/425 on PPE [3]	The product includes instructions for recommended cleaning and/or disinfection materials and processes, if applicable.	*[Include a reference to the product labeling / instructions for use]*

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