# Technical Guidance: **Face Shields**

Updated July 20, 2020

U.S. FDA regulatory info
Classification: Class I (general controls) and 510(k) exempt
Product code: LYU (Accessory, surgical apparel) [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]

## Overview

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

- A concise introduction to the key design features of face shields, 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 face shields, followed by a set of recommended safety and effectiveness criteria that may be used to assess adequate safety and effectiveness



## Contents

## Technical Design and Test Criteria

This section provides a concise introduction to the key design features of face shields, 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 face shields. Demonstrating safety and effectiveness of a medical device is the basis for achieving regulatory approval.

### Overview

Face shields are personal protective equipment (PPE) that are used to protect the wearer's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials. It is typically secured at the crown of the head [5].

### Resistance to Penetration by Splashed or Sprayed Bodily Fluids

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 [6]. There are various international standards that provide an appropriate level of guidance and expectations for demonstrating resistance to splashed or sprayed bodily fluids. The proposed test methods are described below; it is not necessary to perform all test methods (one is sufficient).

#### *ANSI/ISEA Z87.1:2020*

Test method: Demonstrate droplet (splash) protection per ANSI/ISEA Z87.1, American National Standard on Occupational and Educational Personal Eye and Face Protection. The face shield should be appropriately marked with the D3 designation.

#### *ANSI/AAMI PB70:2012*

The FDA emergency use authorization for face shields advised that face shields may provide Level 1 or Level 2 protection ("low or minimal barrier protection") or equivalent per ANSI/AAMI PB70, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities [5].

Test method: Demonstrate Level 1 or Level 2 barrier effectiveness per ANSI/AAMI PB70, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.
Note: impermeable materials (such as clear polyester film) will inherently pass the tests for Level 1 or Level 2 barrier effectiveness, as there will be no water that is able to pass through.

#### *BS EN 166:2002*

Test method: According to BS EN 166:2002, face shields shall be tested in accordance with the methods specified in clause 12 of BS EN 168:2001.

#### *Spray Bottle Test*

Test method: Although not a standardized test method, an acceptable low-fidelity test approach could be to use a typical spray bottle to demonstrate the face shield's ability to protect against splashing or spraying fluids. If available, nontoxic dye could be added to the water to aid the inspection.

### Coverage and Fit

To appropriately protect the wearer's eyes and face from bodily fluids, it is important for the face shield to provide adequate coverage of the front and sides of the face (considering the range of lengths and widths of potential wearers) and ensure a secure but comfortable fit to keep the shield in place. An adjustable band (or similar mechanism) can help ensure a secure fit despite inherent variability in head size and shape.

#### *Use with Eyeglasses*

To ensure the face shield is broadly compatible with potential wearers, it should be able to be worn in conjunction with eyeglasses.

Test method: Qualitatively evaluate the fit of the face shield with various wearers with eyeglasses. The eyeglasses should not interfere with the ability for the face shield to provide adequate coverage.

### *Secure Fit*

The effectiveness of the face shield relies on its proper and maintained positioning on the wearer during normal use. Per BS EN 166:2002 [7], headbands, when used as the principal means of retention, shall be at least 10 mm wide over any portion which may come into contact with the wearer's head.

Test method: Qualitatively evaluate the security of the fit during normal use when wearers (of various head sizes) move their heads from side-to-side and up-and-down in a way that is appropriate during foreseeable use.

## General Construction

Per BS EN 166:2002, the face shield shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use [7].

Test method: Perform a visual inspection to ensure that the face shield is free from projections, sharp edges, or other defects which are likely to cause discomfort or injury during use.

## Visibility

It is imperative that the shield material is transparent so that it does not impair the wearer's vision.

Test method: Assess the optical clarity of the face shield per the applicable requirements of BS EN 166:2002 and associated tests of BS EN 167:2001.

Test method (approximation): Qualitatively evaluate the visibility of the face shield in foreseeable lighting conditions (e.g. compare the visibility of text with and without the face shield in place).

### *Fog Resistance*

If possible, consider the use of a shield material that includes an fog-resistant (anti-fog) coating. This will help ensure optimal visibility during use.

Test method: If the face shield is described as being resistant to fogging, it shall remain free from fogging for a minimum of 8s when tested in accordance with clause 16 of BS EN 168:2001 [7].

## Flame-Resistance (Flame Spread)

The face shield shall meet at least one of the following requirements [5]:

- The face shield does not contain any materials that will cause flammability
- The face shield product meets Class I or Class II flammability requirement per 16 CFR 1610
- The face shield is labeled with a recommendation against use in the presence of high intensity heat source or flammable gas

Test method: If applicable (per above), test the Class I or Class II flammability per 16 CFR 1610, Standard for the Flammability of Clothing Textiles

## Biocompatibility

The band that secures the face shield to the crown of the head 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. Alternatively, the product labeling could include a list of the body-contacting materials (which does not include any drugs or biologics) [5]. In addition, the use of natural rubber latex shall be avoided.

### *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) [8].

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

### *Sensitization*

Sensitization or hypersensitivity reactions may occur in response to repeated or prolonged exposure to a chemical substance [9].

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

### *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 [10].

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



### *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 [11]."

## Regulatory Assessment

### Intended use

Face shields are personal protective equipment (PPE) that are intended to protect the wearer's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials [5].

### Compliance with U.S. FDA Regulatory Requirements

Face shields are categorized under the LYU (Surgical apparel) product code (Figure 1) and are subject to the regulations defined by 21 CFR part 878.4040 (Figure 2). Note that product code LYU and 21 CFR part 878.4040 apply to surgical apparel in general; therefore, the applicability of requirements specifically to face shields must be interpreted.

| | |
|---|---|
| **Device** | Accessory, Surgical Apparel |
| **Regulation Description** | Surgical apparel. |
| **Regulation Medical Specialty** | General & Plastic Surgery |
| **Review Panel** | General Hospital |
| **Product Code** | LYU |
| **Premarket Review** | Infection Control and Plastic Surgery Devices (DHT4B)<br>Infection Control and Plastic Surgery Devices (DHT4B) |
| **Submission Type** | 510(K) Exempt |
| **Regulation Number** | 878.4040 |
| **Device Class** | 1 |
| **Total Product Life Cycle (TPLC)** | TPLC Product Code Report |
| **GMP Exempt?** | No |
| **Summary Malfunction Reporting** | Eligible |

**Note:** FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

| | |
|---|---|
| **Implanted Device?** | No |
| **Life-Sustain/Support Device?** | No |
| **Third Party Review** | Not Third Party Eligible |

*Figure 1 - FDA Product Code for Face Shields [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 2 - Face Shields Regulation 21 CFR 878.4040 [2]*

## 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 3) 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 3 - Preliminary Remarks, Annex II*



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

*Table 1 - Annex II, General Requirements Applicable to All PPE [3]*

| Section 1 Requirement | Applicability to Face Shields |
|---|---|
| **1.1. Design principles** | |
| **1.1.1. Ergonomics**<br>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**, **Fit**, **General Construction**, **Flame-Resistance**, and **Biocompatibility** criteria in Table 4. |
| **1.1.2. Levels and classes of protection**<br>**1.1.2.1. Optimum level of protection**<br>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 **the Resistance to Penetration by Splashed or Sprayed Bodily Fluids** criterion in Table 4. |
| **1.1.2.2. Classes of protection appropriate to different levels of risk**<br>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. | Not applicable – there is only one level of protection for face shields. |
| **1.2. Innocuousness of PPE** | |
| **1.2.1. Absence of inherent risks and other nuisance factors**<br>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**, **Fit**, **General Construction**, **Flame-Resistance**, and **Biocompatibility** criteria in Table 4. |

| Section 1 Requirement | Applicability to Face Shields |
|---|---|
| **1.2.1.1. Suitable constituent materials**<br>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 4. |
| **1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user**<br>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 **General Construction** criterion in Table 4. |
| **1.2.1.3. Maximum permissible user impediment**<br>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. | Applicable; addressed by the **Visibility** criterion in Table 4. |
| **1.3. Comfort and effectiveness** | |
| **1.3.1. Adaptation of PPE to user morphology**<br>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** criteria in Table 4. |
| **1.3.2. Lightness and strength**<br>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. | Applicable; addressed by the **Coverage**, **Fit**, **General Construction**, **Visibility**, and **Flame-Resistance** criteria in Table 4. |
| **1.3.3. Compatibility of different types of PPE intended for simultaneous use**<br>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**<br>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 4. |
| (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 4. |
| (b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE; | Not applicable – there is only one level of protection for face shields. |

| Section 1 Requirement | Applicability to Face Shields |
|---|---|
| (c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts; | Applicable; addressed by the **Instructions for Use – General** criterion in Table 4. |
| (d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use; | Not applicable – there is only one level of protection for face shields. |
| (e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components; | Not applicable – face shields do not have an expiration date. |
| (f) where applicable, the type of packaging suitable for transport; | Not applicable – face shields 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 4. |
| (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; | Not applicable; the technical specifications and standards are set forth in the **Technical Design and Test Criteria** section of this document. |
| (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 2.

*Table 2 - Annex II, Additional Requirements Common to Several Types of PPE [3]*

| Section 2 Requirement | Applicability to Face Shields |
|---|---|
| **2.1. PPE incorporating adjustment systems**<br>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 **Fit** criterion in Table 4. |
| **2.2. PPE enclosing the parts of the body to be protected**<br>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 face shield provides protection to the face without fully enclosing the face or head. |
| **2.3. PPE for the face, eyes and respiratory system**<br>Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.<br><br>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.<br><br>If necessary, such PPE must be treated or provided with means to prevent misting-up. | Applicable; addressed by the **Visibility** and **Fit** criteria in Table 4. |

| Section 2 Requirement | Applicability to Face Shields |
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| 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**<br>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.<br><br>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.<br><br>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 – face shields do not have an expiration date. |
| **2.5. PPE which may be caught up during use**<br>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**<br>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; face shields 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**<br>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.<br><br>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 **Fit** criterion in Table 4. |
| **2.8. PPE for intervention in very dangerous situations**<br>The instructions supplied by the manufacturer with PPE for 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.<br><br>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. | Not applicable |

| Section 2 Requirement | Applicability to Face Shields |
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| 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**<br>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. | Not applicable; face shields do not incorporate adjustable or removable parts for replacement purposes. |
| **2.10. PPE for connection to complementary equipment external to the PPE**<br>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**<br>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; face shields 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**<br>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.<br><br>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**<br>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; face shields are not intended to visually indicate the user's presence. |
| **2.14. Multi-risk PPE**<br>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; face shields are only intended to protect the wearer's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials. |

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

*Table 3 - 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**<br>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.<br><br>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.<br><br>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.<br><br>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.<br><br>The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a | Not applicable; face shields are not intended for the protection of the respiratory system. Face shields are only intended to protect the wearer's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials. |

| Section 3 Requirement | Applicability to Face Shields |
|---|---|
| trained and qualified user to employ the PPE correctly.<br><br>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**<br>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.<br><br>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.<br><br>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 the **Resistance to Penetration by Splashed or Sprayed Bodily Fluids**, **Coverage**, and **Fit** criteria in Table 4. |
| **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],
- EU 2016/425 on PPE [3],
- BS EN 166:2002 [7],
- US FDA emergency use authorization (EUA) for face shields [5],
- 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 face shield design. The objective of this checklist is to provide sufficient confidence that the known and potential benefits outweigh the known and potential risks of face shields for use as PPE; likewise, the known and potential benefits of face shields for use as PPE outweigh the total lack of face shields available for use as PPE.

During the evaluation of a candidate face shield design, Table 4 shall be completed to capture the corresponding evidence and justification for how each criterion is satisfied.

*Table 4 - Essential Criteria to Assure Safety and Effectiveness of Face Shields*

| **Criterion** [Source] | **Description** | **Evidence** *[example rationale or references]* |
|---|---|---|
| PPE design requirements | | |
| **Resistance to Penetration by Splashed or Sprayed Bodily Fluids**<br>21 CFR 878.4040 [2]:<br>(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.<br><br>Refer to 1.1.2.1, 3.10.2 of EU 2016/425 on PPE [3] | The face shield material must be demonstrated to resist the spray of blood and body fluids, including what may be generated through sneezing. | *[Include a reference to the test results that demonstrate the appropriate degree of barrier effectiveness]* |
| **Coverage**<br>Refer to 1.1.1, 1.2.1, 1.3.1, 1.3.2, 3.10.2 of EU 2016/425 on PPE [3] | The face shield provides adequate coverage of the front and sides of the face (considering the range of lengths and widths of potential wearers) and ensure a secure but comfortable fit to keep the shield in place. | *[Include a reference to the dimensional drawing of the face shield]*<br><br>*[Summarize how the coverage adequacy was assessed (e.g. evaluated with healthcare workers)]* |
| **Fit**<br>Refer to 1.1.1, 1.2.1, 1.3.1, 1.3.2, 2.3, 2.7, 3.10.2 of EU 2016/425 on PPE [3] | The face shield provides a secure but comfortable fit to keep the shield in place. | *[Summarize how the fit adequacy was assessed (e.g. evaluated with healthcare workers)]* |

| **Criterion**<br>[Source] | **Description** | **Evidence**<br>*[example rationale or references]* |
|---|---|---|
| | If specified to be compatible with eyeglasses, the fit must additionally be evaluated by wearers with eyeglasses.<br><br>The face shield shall be simple to put on and to take off. | |
| **General Construction**<br>Eye-protectors shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use.<br>BS EN 166:2002 [7]<br><br>Also refer to 1.1.1, 1.2.1, 1.2.1.2, 1.3.2 of EU 2016/425 on PPE [3] | The face shield shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use [7]. | *[The face shield does not have projections, sharp edges, or other defects which are likely to cause discomfort or injury during use.]* |
| **Visibility**<br>Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.<br><br>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.<br><br>If necessary, such PPE must be treated or provided with means to prevent misting-up.<br><br>Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.<br>EU 2016/425 on PPE [3]; see also 1.2.1.3, 1.3.2, 2.3<br><br>See also BS EN 166:2002 [7] | The face shield does not impair the wearer's vision. | *[Summarize how the visibility was assessed (e.g. per BS EN 166:2002 or qualitatively evaluated with healthcare workers)]* |
| **Flame-Resistance**<br>(A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use.<br>21 CFR 878.4040 [2] | The face shield shall meet at least one of the following requirements [5]:<br>• The face shield does not contain any materials that will cause flammability | *[The face shield does not contain any materials that will cause flammability.]*<br><br>*[The face shield meets Class I or Class II flammability requirements per 16 CFR* |

| **Criterion**<br>[Source] | **Description** | **Evidence**<br>*[example rationale or references]* |
|---|---|---|
| Also refer to 1.1.1, 1.2.1, 1.3.2 of EU 2016/425 on PPE [3] | • The face shield meets Class I or Class II flammability requirements per 16 CFR 1610<br>• The face shield is labeled with a recommendation against use in the presence of high intensity heat source or flammable gas | *1610 (and include reference to test report).]*<br><br>*[The face shield is labeled with a recommendation against use in the presence of high intensity heat source or flammable gas.]* |
| **Biocompatibility**<br>(i) The user contacting components of the device must be demonstrated to be biocompatible.<br>21 CFR 878.4040 [2]<br><br>No parts of the eye-protector which are in contact with the wearer shall be made of materials which are known to cause any skin irritation.<br>BS EN 166:2002 [7]<br><br>Also refer to 1.1.1, 1.2.1, 1.2.1.1 of EU 2016/425 on PPE [3] | The band that secures the face shield to the crown of the head 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.<br><br>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* [5]*.]*<br><br>*[Rationale to support that the head band material is not constructed from a known allergen.]*<br><br>*[The product, product container, and product packaging are not made with natural rubber latex.]*<br><br>*[ISO 10993-5:2009 and ISO 10993-10:2010 test reports or material datasheet indicating compliance to these standards.]* |
| (iii) NIOSH approved under its regulation.<br>21 CFR 878.4040 [2] | Evaluate compliance with applicable clauses of ANSI/ISEA Z871. | tbd |
| PPE labeling (includes instructions for use) requirements | | |
| **Instructions for Use – General**<br>Instructions for use shall minimally contain the following information:<br>• Intended use; the risk against which the PPE is designed to protect<br>• Any compatibility constraints with regards to the use of the face shield (e.g. compatible with eyeglasses or not)<br>Refer to 1.4 of EU 2016/425 on PPE [3] | The PPE shall include instructions for use that are easily understandable. | *[Include a reference to the product labeling / instructions for use]* |

| **Criterion**<br>[Source] | **Description** | **Evidence**<br>*[example rationale or references]* |
|---|---|---|
| **Manufacturer Info**<br>(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.<br>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]* |
| **Single/Multi-Use**<br>Product labeling (includes instructions for use) for single user, single use, or multiple uses by the same user.<br>FDA Face Shield EUA [5] | The product is identified as intended for either a single user, single use, or for multiple uses by the same user [5]. | *[Include a reference to the product labeling / instructions for use]* |
| **Cleaning and Disinfection**<br>Product labeling (includes instructions for use) for recommended cleaning and/or disinfection materials and processes, if applicable.<br>FDA Face Shield EUA [5]<br><br>(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;<br>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 [5]. | *[Include a reference to the product labeling / instructions for use]* |
| **General Claims**<br>Product labeling (includes instructions for use), general claims.<br>FDA Face Shield EUA [5] | The product labeling does not state any false claims, such as that the use of the face shield alone will prevent infection from microbes or viruses, or that it is effective against radiation protection [5]. | *[Include a reference to the product labeling / instructions for use]* |

## References


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[3] Official Journal of the European Union, "REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC".

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[12] F2100-19, ASTM, "Standard Specification for Performance of Mateirals Used in Medical Face Masks".