



RWANDA FDA GUIDELINES ON REQUIREMENTS AND SPECIFICATION OF EYE PROTECTORS AND FACE SHIELDS

RWANDA FDA
Rwanda Food and Drugs Authority

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FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018 to regulate matters related to quality, safety and efficacy of regulated products including medical devices.

Based on the available evidence, including the recent publications, WHO continues to recommend droplet and contact precautions for those people caring for COVID-19 patients. WHO continues to recommend airborne precautions for circumstances and settings in which aerosol generating procedures and support treatment are performed, according to risk assessment. Personal protective equipment (PPE) including eye protectors and face shield is one effective measure within a package of administrative and environmental controls, as described in WHO's Infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care.

These guidelines provide guidance on the manufacturer and use of eye protectors and face shields in the current health emergency whereby, there is an urgent need of those products to contain the spread of the pandemic. Adherence to these guidelines will ensure the quality standards and proper use of eye protectors and face shields during this emergency situation.

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ABBREVIATIONS AND ACRONYMS

PPE	Personal protective Equipment
WHO	World Health Organization
COVID	Coronavirus virus disease
SARS	Severe Acute Respiratory syndrome
EN	European Norms
ISO	International Organization for Standardization



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1.1 INTRODUCTION

Rwanda Food and Drugs Authority (Rwanda FDA) plays a critical role in protecting public health in Rwanda through ensuring the compliance of quality standard of regulated products including eye protectors and face shield as in the category of Personal Protective equipment (PPE). COVID-19 is currently known to spread through four means: contact (direct or via a fomite); droplet infection (droplets from the respiratory tract of an infected individual during coughing or sneezing are transmitted onto a mucosal surface or conjunctiva of a susceptible individual or environmental surfaces); airborne (transmission of infectious agents in small airborne particles, particularly during procedures such as intubation); and fecal-oral.

As this pandemic is expanding, more health care providers are requiring eye protectors and face shields. It is important that healthcare personnel that even if droplet Precautions are not recommended for a specific respiratory tract pathogen, protection for the eyes, nose and mouth by using a mask and goggles, or face shield alone, is necessary when it is likely that there will be a splash or spray of any respiratory secretions or other body fluids. Eye protection must be comfortable, allow for sufficient peripheral vision, and must be adjustable to ensure a secure fit. Rwanda FDA issues these guidelines to guide manufacturers and users of eye protectors and face shield.

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1.2 BACKGROUND

Currently, the outbreak of respiratory disease caused by a novel coronavirus that was first detected in Wuhan City, Hubei Province, China, has also been detected in Rwanda and WHO declared the Coronavirus outbreak (COVID-19) as pandemic.

The virus has been named “Severe Acute Respiratory Syndrome” (SARS CoV-2) and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). SARS-CoV-2 has demonstrated the capability to rapidly spread, leading to significant impact on healthcare systems and causing societal disruption and deaths. The potential public health threat posed by COVID-19 is high, both globally and in Rwanda.

Throughout this pandemic, the number of patients globally and in Rwanda is increasing and more of personal protective equipment are needed including eye protectors and Face shields. Rwanda FDA believes that the current guidelines will help address these public health concerns by clarifying the regulatory landscape of eye protectors and face shield facilitating those who wants to manufacture or import these eye protectors and face shield. This will increase their availability in healthcare settings.

Rwanda FDA issues these guidelines for guiding manufacturers for manufacturing appropriate eye protectors and face shields, will also guide importers and users on specifications of these equipment and how they will be used in hospital settings.

1.3 SCOPE THESE GUIDELINES

The scope for these guidelines is for eye protectors and face shields to be used in the hospital setting, these guidelines include various types and incorporates general considerations such as:

- general requirements
- designation;
- classification;
- basic requirements applicable to all eye-protectors and face shield;

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- various particular and optional requirements;
- allocation of requirements, testing and application;
- marking;
- information for users.

2. NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of these guidelines some are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited and latest edition of the referenced document (including any amendments) applies.

EN 166: Personal eye-protection - Specifications

EN 165: Personal eye-protection -Vocabulary .

EN 167:2001: Personal eye-protection - Optical test methods

EN 168:2000: Personal eye-protection - Optical test methods

ISO 8980-1: Ophthalmic optics - uncut finished

SECTION I: REQUIREMENTS AND SPECIFICATIONS

I.1 DEFINITIONS

Eye protector

personal protective equipment that is worn or held with the intention of protecting at least the region of the eye

Face shield

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protector that is worn directly or indirectly on the head and covers the eyes and all, or a substantial part, of the face

A face screen can be mounted by help of an adjustable or non-adjustable means of fixing onto a protective or non-protective helmet, or on the head, either directly or by help of an adjustable or non-adjustable means of fixing onto a support (headband) and/or harness.

Goggle

protector that fully encloses the orbital area and fits firmly on the face

Spectacles

Protector in a spectacle configuration that is supported principally on the nose and ears rather than on the head

Safety

“safe” is the state of being protected from recognized hazards that are likely to cause harm where some level of risk is inherent in products or systems.

Harm

injury or damage to the health of people, or damage to property or the environment

Hazard

potential source of harm

Risk

combination of the probability of occurrence of harm and the severity of that harm

Optical radiation

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electromagnetic radiation at wavelengths between the region of transition to X-rays ($\lambda \approx 1 \text{ nm}$) and the region of transition to radio waves ($\lambda \approx 1 \text{ mm}$)

Note: Optical radiation is usually subdivided into the following spectral ranges, with a possible overlap at the longer wavelength limit of the UV spectrum:

- ultraviolet radiation ;
- visible radiation ;
- infrared radiation

I.2 General Description

I.2.1 Eye protectors

General description	Specifications
General construction	Eye-protectors shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use.
Materials	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.
Headbands (Where application)	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. Headbands shall be adjustable or self-adjusting
Field of vision	Eye-protectors shall exhibit a minimum field of vision
Spherical. Astigmatic & Prismatic refractive powers	The visor must not affect the wearers vision or strain their eyes
Quality of material and surface	Except for a marginal area 5 mm wide, the

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	visors shall be free from any significant defects likely to impair vision in use, such as bubbles, scratches, inclusions, dull spots, pitting, mould marks, scouring, grains, pocking, scaling and undulation.
Latex protection	The face shield protects from at least 10mm at the corner of the eyes

I.2.2. Face shield

The general description of face shields is the following:

- a. Made of clear plastic and provides good visibility to both the wearer and the patient
- b. Adjustable band to allow good fit around the head and snug fit against the forehead
- c. Fog-resistant (preferable)
- d. Completely covers the sides and length of the face
- e. May be reusable (made of material that can be cleaned and disinfected) or disposable.
- f. Material, shield part: clear polycarbonate and polyester (PET) Film, thickness approx. 0.3 mm
- g. Material also can be: Ethyl vinyl acetate (EVA)/Plastazote, flexible and heat moldable foam, 180mm(length), 35mm (width) and 24 mm (thickness)
- h. Head Band : Non elastic and thick clothing: 210 mm (length), 2mm (thickness) and 30 mm (width)
- i. Adjustable length headband, integrated with the shield
- j. Shield is anti-fog treated/coated
- k. Outside is coated to prevent glare from reflection

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I.3 Classification

I.3.1 Function of eye-protectors

The function of eye-protectors is to provide protection against:

- impacts of different severities; optical radiations; molten metals and hot solids; droplets and
- splashes; dust; gases; short circuit electric arc; or any combination of these.

I.3.2 Types of eye-protectors

- i) Spectacles with or without lateral protection
- ii) Goggles
- iii) Face-shields

I.3.3 Types of ocular

I.3.3.1 Mineral oculars (glass)

- i) Untoughened mineral oculars
- ii) Toughened mineral oculars, toughened chemically, thermally or by other processes to give superior resistance to impact in comparison with untoughened mineral oculars.

I.3.3.2 Organic oculars (plastic)

I.3.3.2.1 Laminated oculars

Oculars made in multiple layers joined together by a binder.

They may also be classified as oculars with corrective effect and oculars without corrective effect. They may also have coatings on their surface(s) to give additional characteristics.

I.3.4 Designation of filters

The transmittance characteristics of a filter are represented by a scale number, which is combination of the code number and the shade number of the filter, joined together by a dash.

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The scale number for welding filters does not include a code number, it comprises the shade number only.

Table 1: Scale numbers for filters

Welding filters	Ultraviolet filters		Infrared filters	Filters for sun glare	
No number code	Code number 2	Code number 3	Code number 4	Code number 5	Code number 6
Scale number					
1,2	2 – 1,2	3 – 1,2	4 – 1,2	5 – 1,1	6 – 1,1
1,4	2 – 1,4	3 – 1,4	4 – 1,4	5 – 1,4	6 – 1,4
1,7		3 – 1,7	4 – 1,7	5 – 1,7	6 – 1,7
2		3 – 2	4 – 2	5 – 2	6 – 2
2,5		3 – 2,5	4 – 2,5	5 – 2,5	6 – 2,5
3		3 – 3	4 – 3	5 – 3,1	6 – 3,1
4		3 – 4	4 – 4	5 – 4,1	6 – 4,1
4a					
5		3 - 5	4 - 5		
5a					
6			4 - 6		
6a					
7			4 – 7		
7a					
8			4 – 8		
9			4 – 9		

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10			4 - 10		
11					
12					
13					
14					
15					
16					

NOTE Code number key:

- 2 Ultraviolet filter, colour recognition may be affected;
- 3 Ultraviolet filter, good colour recognition;
- 4 Infra-red filter;
- 5 Sun glare filter without infrared specification;
- 6 Sun glare filter with infrared specification.

I.4. General construction

Eye-protectors shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use.

I.5. Materials

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.

I.6. Headbands

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. Headbands shall be adjustable or self-adjusting.

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I.7. Basic, particular and optional requirements

All eye-protectors shall meet the basic requirements including field of vision, particular requirements such as protection against optical radiation and other optical requirements

Furthermore, according to their intended use, eye-protectors shall, if appropriate, meet one or more of the particular requirements given in section of particular requirements and optional requirements related to additional properties of eye-protectors.

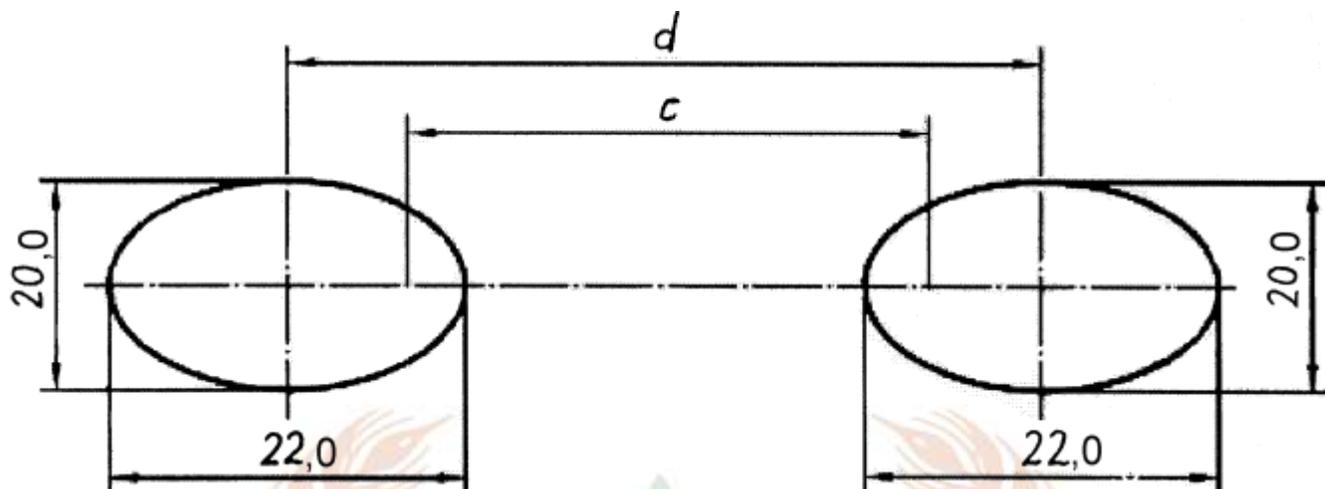
I.8. Basic requirements

I.8.1 Field of vision

The size of the field of vision is defined in conjunction with the appropriate head-form Eye-protectors shall exhibit a minimum field of vision defined by the two ellipses in **Figure 1** when placed and centered at a distance of 25 mm from the surface of the eyes of the appropriate head-form. The horizontal axis shall be parallel to and 0,7 mm below the height of the line connecting the centers of the two eyes.

The horizontal length of the ellipses shall be of 22,0 mm, the vertical width of the ellipses shall be 20,0 mm. The center distance of the two ellipses shall be $d = c + 6$ mm, where c is the pupillary distance. The pupillary distance is 64 mm for the medium head-form and 54 mm for the small head-form, if not specified differently by the manufacture.

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Optical requirements

I.8.2 Spherical, astigmatic and prismatic refractive powers

The refractive powers of oculars shall be measured in reference to international recognized methods.

I.8.2.1 Unmounted oculars covering one eye

The refractive power characteristics of unmounted oculars covering one eye shall be measured by international recognized methods (non-corrective oculars),

The permissible tolerances for oculars without corrective effect are given in **Table 1**.

The permissible deviations for the vertex powers of oculars with corrective effect are specified in EN ISO 8980-1 and EN ISO 8980-2.

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Table 2: Permissible tolerances for refractive powers of unmounted oculars without corrective effect covering one eye

Optical class	Spherical refractive power $(D_1 D_2)/2$ m-1	Astigmatic refractive power $ D_1 D_2 $ m-1	Prismatic refractive power cm/m
1	0,06	0,06	0,12
2	0,12	0,12	0,12

NOTE D_1 and D_2 are the refractive powers in the two principal meridians.

I.8.2.2 Mounted oculars and unmounted oculars covering both eyes

The refractive power characteristics of mounted oculars or unmounted oculars covering both eyes shall be measured by the method specified in 3.2 of EN 167:2001 at the visual center of the ocular.

The permissible tolerances for oculars without corrective effect are given in **Table 2**.

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Table 3 — Permissible tolerances for refractive powers of mounted oculars without corrective effect and unmounted oculars without corrective effect covering both eyes

Optical class	Spherical refractive power $(D_1 D_2)/2$ m-1	Astigmatic refractive power $ D_1 D_2 $ m-1	Difference in prismatic refractive power		
			cm/m		Vertical
			Horizontal	Vertical	
			Base out	Base in	
1	$\pm 0,06$	0,06	0,75	0,25	0,25
2	$\pm 0,12$	0,12	1,00	0,25	0,25
3	+ 0,12 – 0,25	0,25	1,00	0,25	0,25

NOTE D_1 and D_2 are the refractive powers in the two principal meridians. For optical class 3 the axes of the principal meridians shall be parallel within 10° .

I.8.2.3 Deviations that would correspond to class 3 shall not be permitted.

The difference in prismatic refractive power specified for an eye-protector depends not only on the prismatic refractive power of each ocular, but also on the position of the optical axis of the ocular in relation to the axis of vision, and therefore the shape of the frame. It is therefore necessary to use replacement oculars for which the difference in prismatic power remains within the permissible tolerance limits for the frame in question.

I.8.3 Cover plates

The refractive powers of cover plates shall comply with the tolerances for optical class 1 given in **Table 2** and **Table 3**.

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I.8.4 Transmittance

I.8.4.1 Oculars without filtering action

Oculars intended to protect the eyes against mechanical or chemical hazards only, and cover plates, shall have a luminous transmittance greater than 74,4 % when measured as given in clause 6 of EN 167:2001.

I.8.4.2 Oculars with filtering action (filters) and housings for oculars with filtering action.

The transmittance of oculars with filtering action shall meet the requirements given in the specific standards relating to the various types of ocular

Goggles and face-shields which claim to provide protection against optical radiation shall provide at least the same level of protection against optical radiation as given by a filter of any scale number declared usable with the eye protector by the manufacturer or supplier.

I.8.4.3 Variations in transmittance (Oculars without filtering action are exempt from this requirement)

i) Oculars without corrective effect

The relative variations of the luminous transmittance around the visual center(s) P 1 (and P 2) shall not exceed the values of **Table 4**.

Table 4 — Variations in luminous transmittance

Luminous transmittance		Permissible relative variation
less than %	up to %	
100	17,8	± 5
17,8	0,44	± 10
0,44	0,023	± 15
0,023	0,0012	± 20
0,0012	0,000023	± 30

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The relative difference in luminous transmittance P 3 between left and right eye shall not exceed the values of Table 4 or 20 % whichever is greater.

ii) Oculars with corrective effect (prescription oculars)

The requirements shall also apply to prescription oculars, with the provision that variations in luminous transmittance which are due to thickness variations inherent in the design of the ocular are not taken into account, providing the luminous transmittance at no point deviates by more than a factor of 2,68 (one shade number) from its value at the visual center. The IR and UV transmittance shall meet the requirements of the specified shade number at every point on the ocular.

I.8.4.4 Diffusion of light

The diffusion of light shall be measured in accordance with one of the reference international recognized methods.

The maximum value of the reduced luminance factor shall be:

cd

1,00 _____ for

welding filters;

$m^2 lx cd$

0,75 _____ for oculars used in eye-protectors against high

speed particles; $m^2 lx cd$

0,50 _____ for all other

oculars. $m^2 lx$

I.8.4.5 Quality of material and surface

Except for a marginal area 5 mm wide, oculars shall be free from any significant defects likely to impair vision in use, such as bubbles, scratches, inclusions, dull spots, pitting, mould marks, scouring, grains, pocking, scaling and undulation.

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The assessment shall be carried out in accordance with the method specified in accordance with international recognized methods.

I.8.4.6 Robustness

I.8.4.6.1 Minimum robustness

This requirement relates only to cover plates and oculars with filtering effect and need not be assessed if these items are intended to meet the requirements for increased robustness or resistance to high speed particles,

The requirement for minimum robustness is satisfied if the ocular withstands the application of a 22 mm nominal diameter steel ball with a force of (100 ± 2) N, when tested in accordance with international recognized methods.

On so testing the following defects shall not occur:

a) ocular fracture: an ocular shall be considered to have fractured if it cracks through its entire thickness into two or more pieces, or if more than 5 mg of the ocular material becomes detached from the surface away from the one in contact with the ball, or if the ball passes through the ocular;

b) ocular deformation: an ocular shall be considered to have been deformed if a mark appears on the white paper on the opposite side to the one on which the force is applied.

I.8.4.6.2 Increased robustness

i) Unmounted oculars

The oculars shall withstand the impact of a 22 mm nominal diameter steel ball, of 43 g minimum mass, striking the ocular at a speed of approximately 5,1 m/s, when tested in accordance with international recognized methods.

On so testing the following defects shall not occur:

a) ocular fracture; an ocular shall be considered to have fractured if it cracks through its entire thickness into two or more pieces, or if more than 5 mg of the ocular material becomes detached from the surface away from the one struck by the ball, or if the ball passes through the ocular;

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b) ocular deformation; an ocular shall be considered to have been deformed if a mark appears on the white paper on the opposite side to that struck by the ball.

ii) Complete eye-protectors and frames

The complete eye-protector or frame shall withstand the lateral and frontal impacts of a steel ball striking at a specified speed.

The diameter of the steel ball and the corresponding impact speed are given in **Table 5**.

Table 5 — Requirements relating to increased robustness of complete eye-protectors

Size, mass and speed of steel ball	Spectacles		Goggles		Face-shields
	Frontal impact	Lateral impact	Frontal impact	Lateral impact	
22 mm nominal diameter steel ball, of 43 g minimum mass, at a speed of approximately 5,1 m/s	✓	✓	✓	✓	✓

The test shall be in accordance with the method specified in international recognized methods.

If a spectacle is claimed to have lateral protection it shall not be possible for the ball to strike the lateral impact points without first striking the lateral protection.

On so testing the following defects shall not occur:

a) ocular fracture: an ocular shall be considered to have fractured if it cracks through its entire thickness into two or more pieces, or if more than 5 mg of the ocular material becomes detached from the surface away from the one struck by the ball, or if the ball passes through the ocular;

b) ocular deformation: an ocular shall be considered to have been deformed if a mark appears on the white paper on the opposite side to that struck by the ball;

c) ocular housing or frame fracture: an ocular housing or frame shall be considered to have failed if it separates into two or more pieces, or if it is no longer capable of holding an ocular in

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position, or if an unbroken ocular detaches from the frame, or if the ball passes through the housing or frame

d) lateral protection failure: the lateral protection shall be considered to have failed if it fractures through its entire thickness into two or more separate pieces, or if one or more particles become detached from the surface remote from the impact point, or if it allows the ball to penetrate completely, or if it partially or totally detaches from the eye-protector, or if its component parts become separated.

I.8.4.6 Resistance to ageing

Cover plates and glass oculars are exempt from these tests. The exemption does not apply to coated or laminated glass.

I.8.4.7 Stability at an elevated temperature

Assembled eye-protectors shall show no apparent deformation when tested by the method specified in international recognized methods.

I.8.4.8 Resistance to ultraviolet radiation (oculars only)

Oculars shall be subjected to the test for resistance to ultraviolet radiation in accordance with the method specified in international recognized methods.

At the end of the test, oculars shall meet the following requirements.

The relative change of luminous transmittance shall not be greater than the values specified in the following **Table 6**.

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Luminous transmittance		Permissible relative change
less than	up to	
%	%	%
100	17,8	± 5
17,8	0,44	± 10
0,44	0,023	± 15
0,023	0,0012	± 20
0,0012	0,000023	± 30

If for welding filters the relative change of the luminous transmittance is larger than the values specified in **Table 6** but the actual value of luminous transmittance remains within the range specified by its shade number, a second irradiation is performed in accordance with international recognized methods on the same sample. The relative change of luminous transmittance due to the second irradiation shall not be greater than the values specified in **Table 6** and the actual value of luminous transmittance shall remain within the range specified by its shade number;

- a) The value of the reduced luminance factor shall not exceed the permissible limits given in specifications

Table 7 — Requirements relating to protection against high-speed particles

Type of eye-protector	Impact speed of ball		
	Low energy impact (F)	Medium energy impact (B)	High energy impact(A)
	451,5 m/s	120 ³ ₀ m/s	190 ⁵ ₀ m/s
Spectacles	+	Not applicable	Not applicable
Goggles	+	+	Not applicable

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Face-shields	+	+	+
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I.8.4.9 Resistance to corrosion

After having undergone the test for resistance to corrosion specified in international recognized methods, all metal parts of the eye-protector shall display smooth surfaces, free from corrosion, when they are examined by a trained observer.

I.8.4.10 Resistance to ignition

Eye-protectors shall be tested in accordance with the method specified in international recognized methods and shall be considered to be satisfactory if no part of the eye-protector ignites or continues to glow after removal of the steel

I.8.5 Protection against high-speed particles

Eye-protectors intended to provide protection against high-speed particles shall withstand the impact of a 6 mm nominal diameter steel ball of 0,86 g minimum mass, striking the oculars and the lateral protection at one of the speeds given in **Table 7**.

Eye-protectors for protection against high-speed particles shall also meet the requirements for increased robustness.

Table 7 — Requirements relating to protection against high-speed particle

Type of eye-protector	Impact speed of ball		
	Low energy impact (F)	Medium energy impact (B)	High energy impact(A)
	451,5 m/s	120 ³ m/s	190 ⁵ m/s
Spectacles	+	Not applicable	Not applicable
Goggles	+	+	Not applicable

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Face-shields	+	+	+
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The test shall be in accordance with the method specified in international recognized methods. It shall not be possible for the ball to strike the lateral impact point without first striking the lateral protection.

On so testing the following defects shall not occur:

- a) ocular fracture:** an ocular shall be considered to have fractured if it cracks through its entire thickness into two or more pieces, or if more than 5 mg of the ocular material becomes detached from the surface away from the one struck by the ball, or if the ball passes through the ocular;
- b) ocular deformation:** an ocular shall be considered to have been deformed if a mark appears on the white paper on the opposite side to that struck by the ball;
- c) ocular housing or frame failure:** an ocular housing or frame shall be considered to have failed if it separates into two or more pieces, or if it is no longer capable of holding an ocular in position, or if an unbroken ocular detaches from the frame, or if the ball passes through the housing or frame;
- d) lateral protection failure:** the lateral protection shall be considered to have failed if it fractures through its entire thickness into two or more separate pieces, or if one or more particles becomes detached from the surface remote from the impact point, or if it allows the ball to penetrate completely, or if it partially or totally detaches from the eye-protector, or if its component parts become separated.

I.8.6 Protection against molten metals and hot solids

Eye-protectors intended to provide protection against molten metals and hot solids shall be considered to be satisfactory if:

- a) the eye-protector is either a goggle or a face-shield;
- b) the viewing area of oculars for face-shields has a minimum vertical center-line depth of 150 mm when mounted in the appropriate housing;

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- c) face-shields cover the eye-region rectangle of the appropriate head-form as assessed in accordance with international recognized methods;
- d) the eye-protector satisfies the requirements for one of the three impact energy categories
- e) when tested and assessed in accordance with international recognized methods. They prevent the adherence of molten metal to the portion of the eye-protector which affords protection to the eye-region.
- f) complete penetration of oculars for goggles, and all types of frames, housings, browguards, etc. does not occur within 7 s when tested as described in accordance with international recognized methods;
- g) complete penetration of oculars for face-shields does not occur within 5 s when tested as described in accordance with international recognized methods.

I.8.7 Protection against droplets and splashes of liquids

While goggles help protect a wearer's eyes from splashes, sprays, and droplets, a face shield can help reduce exposure to both the eyes and other facial areas. Face shields, whether disposable or reusable, should cover the front and sides of the face.

Eye-protectors for use against droplets (goggles) and splashes of liquids (face-shields) shall be tested in accordance with the methods specified in accordance with international recognized methods. The results shall be considered to be satisfactory if:

- a. no pink or crimson coloration appears in the ocular regions defined by the two circles when assessing goggles for protection against droplets. No account shall be taken of any such coloration up to a distance of 6 mm inside the edges of the eye-protector;
- b. face-shields cover the eye-region rectangle of the appropriate head-form as described in 10.2.2.2 of EN 168:2001 as assessed in accordance with international recognized methods

Additionally, face-shields for protection against splashes of liquids shall have a viewing area with a minimum vertical center-line depth of 150 mm when mounted in the appropriate housing.

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I.8.8 Protection against large dust particles

Eye protectors fall under the category of PPE or personal protective equipment, and generally serve to protect health workers and consumers from hazards including large particles exposed on the healthcare providers.

Eye-protectors for use against large dust particles shall be tested in accordance with the method specified in accordance with international recognized methods. The result shall be considered to be satisfactory if the reflectance after the test is not less than 80 % of its value before the test.

I.8.9 Protection against gases and fine dust particles

Eye-protectors for use against gases and fine dust particles shall be tested in accordance with the method specified as per recognized relevant test methods. They shall be regarded as satisfactory if no pink or crimson coloration appears in the area covered by the eye-protector. No account shall be taken of any such coloration up to a distance of 6 mm inside the edges of the eye-protector.

I.8.10 Protection against short circuit electric arc

Eye-protectors for protection against short circuit electric arc shall be face-shields only. They shall have no exposed metal parts and all external edges of the protector shall be radiused, chamfered or otherwise treated to eliminate sharp edges. Oculars shall have a minimum thickness of 1,4 mm and a scale number

I.8.11 Lateral Protection

Eye-protectors claimed to provide lateral protection shall pass the lateral region coverage.

I.9 Optional requirements

Optional requirements are specified for additional characteristics of eye-protectors which may be found to be beneficial to the user for operational reasons.

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I.9.1 Resistance to surface damage by fine particles

If oculars are described as resistant to surface damage by fine particles they shall have a reduced luminance factor

I.9.2 Resistance to fogging of oculars

If oculars are described as resistant to fogging they shall remain free from fogging for a minimum of 8 s.

This procedure does not assess resistance to fogging of the complete eye-protector.

I.9.3 Oculars with enhanced reflectance in the infrared

Oculars which are claimed to have enhanced reflectance in the infrared shall have a mean spectral reflectance greater than 60 % within the wavelength range 780 nm to 2 000 nm when measured as per recognized relevant test methods.

I.9.4 Protection against high speed particles at extremes of temperature

Eye-protectors intended to provide protection against high-speed particles at extremes of temperature shall withstand the impact of a 6 mm nominal diameter steel ball of 0,86 g minimum mass, striking the oculars and the lateral protection at one of the speeds given in **Table 7**. The impacts are carried out after the eye-protectors have been conditioned at extremes of temperature ((55 ± 2) °C and (-5 ± 2) °C).

It shall not be possible for the ball to strike the lateral impact point without first striking the lateral protection.

On so testing the following defects shall not occur:

- a. **ocular fracture:** an ocular shall be considered to have fractured if it cracks through its entire thickness into two or more pieces, or if more than 5 mg of the ocular material becomes detached from the surface away from the one struck by the ball, or if the ball passes through the ocular;

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- b. **ocular deformation:** an ocular shall be considered to have been deformed if a mark appears on the white paper on the opposite side to that struck by the ball;
- c. **ocular housing or frame failure:** an ocular housing or frame shall be considered to have failed if it separates into two or more pieces, or if it is no longer capable of holding an ocular in position, or if an unbroken ocular detaches from the frame, or if the ball passes through the housing or frame;
- d. **lateral protection failure:** the lateral protection shall be considered to have failed if it fractures through its entire thickness into two or more separate pieces, or if one or more particles becomes detached from the surface remote from the impact point, or if it allows the ball to penetrate completely, or if it partially or totally detaches from the eye-protector, or if its component parts become separated.

SECTION II: MARKING, LABELLING AND INSTRUCTIONS TO USERS

II.1 Marking

II.1.1 General

All markings shall be clear and permanent.

The marking shall be fully visible when the complete eye-protector is assembled and shall not encroach into the minimum field of vision. Outside of this area the marking shall not impede vision when worn.

The number of this standard shall be applied to frames and housings but need not be applied to oculars.

The frame and ocular shall be marked separately. If the ocular and frame form a single unit, the complete marking shall be applied to the frame

II.2 Labelling

The manufacturer shall provide with each eye-protector, replacement ocular and replacement frame at least the following information have to appear on the eye protectors and face shield:

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- a. Name and specification of the eye protectors, spare parts and face shield
- b. Name of the manufacturer;
- c. instructions for storage, use and maintenance;
- d. specific instructions for cleaning and disinfection;
- e. details of the field of use, protection capabilities and performance characteristics;
- f. details of suitable accessories and spare parts. Instructions for fitting shall be included with the original eye protector and/or with the spare part or accessory;
- g. the obsolescence deadline or period of obsolescence, if applicable, for the complete eye-protector and/or component parts;
- h. the type of packaging suitable for transport, if applicable;
- i. the significance of the marking on the frame and the ocular;
- j. a warning that optical class 3 oculars are not intended for long term use, if applicable;
- k. a warning that materials which may come into contact with the wearer's skin could cause allergic reactions to susceptible individuals;
- l. a warning that scratched or damaged oculars should be replaced;
- m. a warning that eye-protectors against high speed particles worn over standard ophthalmic spectacles may transmit impacts, thus creating a hazard to the wearer.

II.3. Use of eye protectors and Face shields

- a) Health care providers must wear the eye protectors and or face shields when providing direct care to COVID-19 patients especially when Aerosol-generating procedures is being performed on COVID-19 patients,
- b) Laboratory technician when performing Manipulation of respiratory samples

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- c) Eye protector can be worn when performing physical examination of patient with respiratory symptoms
- d) If goggles with temples are used, make sure that they are properly positioned and fit well
- e) While wearing gloves, carefully wipe the inside, followed by the outside of the face shield or goggles using a clean cloth saturated with neutral detergent solution or cleaner wipe.
- f) Carefully wipe the outside of the face shield or goggles using a wipe or clean cloth saturated with disinfectant solution.
- g) Wipe the outside of face shield or goggles with clean water or alcohol to remove residue.
- h) Fully dry (air dry or use clean absorbent towels)

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3. CDC, Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, July 2019,

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