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Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications —

Part 1: Specification for products

Équipements ophtalmiques de protection contre les sources lumineuses intenses utilisées sur les animaux et les humains pour des applications médicales et cosmétiques —

Partie 1: Spécifications des produits

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 6, *Eye and face protection*.

ISO 12609 consists of the following parts, under the general title *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications*:

— *Part 1: Specification for products*

— *Part 2: Guidance for use*

Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications —

Part 1:
Specification for products

1 Scope

This part of ISO 12609 specifies performance and labelling of eye protectors used for ILS equipment used on humans and animals for cosmetic and medical applications against excessive exposure to optical radiation in the spectral range 250 nm to 3 000 nm, with the exception of laser radiation.

This part of ISO 12609 provides a specification for an eye protector expected to cope with the majority of applications. A more rigorous procedure for determining appropriate eye protection against spectral outputs from ILS equipment is described in the annexes.

This part of ISO 12609 is not applicable to eye protectors for use with tanning equipment, ophthalmic instruments or other medical/cosmetic devices, the safety issues of which are addressed through other European and International standards.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies

ISO 12311:2013, *Personal protective equipment — Test methods for sunglasses and related equipment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
blue light hazard
potential for a photochemically induced retinal injury resulting from optical radiation exposure in the wavelength range 300 nm to 700 nm

3.2
filter protection factor
FPF
factor by which the filter attenuates the weighted ocular exposure

Note 1 to entry: Mathematical expressions for FPF are given in Annex A and example calculations in Annex B and Annex C.

3.3
infra-red lens hazard
potential for a thermal injury to cornea and lens of the eye resulting from optical radiation exposure in the wavelength range 780 nm to 3 000 nm

3.4
intense light source
ILS
device incorporating one or more non-laser sources of optical radiation of the wavelength range 250 nm to 3 000 nm and intended for creating biological effects in humans and animals

Note 1 to entry: It can operate in a continuous or pulsed regime.

3.5
retinal thermal hazard
potential for a thermal retinal injury resulting from optical radiation exposure in the wavelength range 380 nm to 1 400 nm

3.6
ultraviolet hazard
potential for skin and ocular acute and chronic adverse effects resulting from optical radiation exposure in the wavelength range 250 nm to 400 nm

4 Transmittance

4.1 General

The spectral transmittance of the ILS eye protector at the wavelengths between 250 nm and 3 000 nm shall be specified.

The spectral transmittance $\tau(\lambda)$ of the eye protector material shall be determined for normal incidence. The wavelength shall be determined at not more than 10 nm intervals with the central wavelength known to within ± 2 nm from 250 to 800 nm and within ± 4 nm above 800 nm. The bandwidth of the detector (full width half maximum) shall not exceed 5 nm.

Filters with angular dependent transmittance shall be measured at angles of incidence between at least 0° and 30°.

In addition, ILS eyewear may be designated F- or B- scale numbers according to 4.2 and/or 4.3.

4.2 F-classification

ILS eyewear may be designated F-scale number using the F-classification scheme described in Table 1.

NOTE The F-numbers in Table 1 are related to the shade numbers with some relaxation in the infrared region.

Luminous transmittance shall be determined according to 4.4.

Table 1 — Transmittance requirements for general purpose ILS filters

Scale number	Maximum spectral transmittance in the ultraviolet spectral range $\tau(\lambda)$			Luminous transmittance τ_v		Maximum mean transmittance in the infrared spectral range τ_{NIR}
	250 nm to 315 nm %	>315 nm to 380 nm %	>380 nm to 450 nm	Maximum %	Minimum %	780 nm to 3 000 nm %
F-1	0,1	0,4	τ_v	100	43,2	50
F-2	0,1	0,4	τ_v	43,2	17,8	50
F-3	0,1	0,4	τ_v	17,8	8,5	50
F-4	0,1	0,4	τ_v	8,5	3,2	50
F-5	0,1	0,4	τ_v	3,2	1,2	50
F-6	0,1	0,4	τ_v	1,2	0,44	50

4.3 B-classification

In many types of ILS it is the blue component of light that poses the greatest risk. To take account of this, a 'blue light' B-classification scheme described in Table 2 may be used.

Blue light transmittance τ_B should be determined as:

$$\tau_B = \frac{\int_{\lambda=380}^{\lambda=550} E(\lambda)B(\lambda)\tau(\lambda)d\lambda}{\int_{\lambda=380}^{\lambda=550} E(\lambda)B(\lambda)d\lambda} \times 100\,\%$$

where

$E(\lambda)$ is the spectral irradiance of the CIE Standard Illuminant D65, in W m^{-2} nm^{-1};

$B(\lambda)$ is blue light hazard weighting function (see Annex D);

$\tau(\lambda)$ is the spectral transmittance of filter material at wavelength λ;

$\Delta\lambda$ is the wavelength interval of the measurements, in nm.

Table 2 — Transmittance requirements for blue light ILS filters

Scale number	Maximum spectral transmittance in the ultraviolet spectral range $\tau_{UV}(\lambda)$			Blue light transmittance τ_B		Maximum mean transmittance in the infrared spectral range $\tau_{NIR}(\lambda)$
	250 nm to 315 nm %	>315 nm to 380 nm %	>380 nm to 450 nm	Maximum %	Minimum %	780 nm to 3 000 nm %
B-1	0,1	0,4	τ_B	100	43,2	50
B-2	0,1	0,4	τ_B	43,2	17,8	50
B-3	0,1	0,4	τ_B	17,8	8,5	50
B-4	0,1	0,4	τ_B	8,5	3,2	50
B-5	0,1	0,4	τ_B	3,2	1,2	50
B-6	0,1	0,4	τ_B	1,2	0,44	50

4.4 Luminous transmittance

The luminous transmittance τ_V of the protective filters intended for use by the ILS operator shall be determined as:

$$\tau_V = \frac{\int_{\lambda=380}^{\lambda=780} E(\lambda)V(\lambda)\tau(\lambda)d\lambda}{\int_{\lambda=380}^{\lambda=780} E(\lambda)V(\lambda)d\lambda}$$

where

$E(\lambda)$ is the spectral irradiance of the CIE Standard Illuminant D65, in W m^{-2} nm^{-1};

$V(\lambda)$ is spectral luminous efficiency;

$\Delta\lambda$ is the wavelength interval of the measurements, in nm;

$\tau(\lambda)$ is the spectral transmittance of filter material at wavelength λ.

NOTE There are no requirements for the luminous transmittance of the filters of eye protectors intended for use by ILS equipment patients/clients; these filters may be opaque.

5 Colour recognition

5.1 General

There are no requirements for colour neutrality.

If colour neutrality is claimed, spectral transmittance between 450 nm and 650 nm shall be uniform within ± 20 % of the mean transmittance value in this range.

5.2 Colour of the protective filters

The Commission Internationale de L'Eclairage (CIE) colour coordinates (x, y) of the protective filters intended for use by the ILS operator shall be determined as:

$$x = \frac{X}{X+Y+Z}$$

and

$$y = \frac{Y}{X+Y+Z}$$

where

$$X = \int_{\lambda=380}^{\lambda=780} \tau(\lambda)E(\lambda)\bar{x}(\lambda)d\lambda$$

$$Y = \int_{\lambda=380}^{\lambda=780} \tau(\lambda)E(\lambda)\bar{y}(\lambda)d\lambda$$

$$Z = \int_{\lambda=380}^{\lambda=780} \tau(\lambda)E(\lambda)\bar{z}(\lambda)d\lambda$$

and

$\bar{x}, \bar{y}$ and $\bar{z}$ are CIE colour matching functions;

$E(\lambda)$ is the spectral irradiance of the CIE Standard Illuminant D65, in W m^{-2} nm^{-1};

$\Delta\lambda$ is the wavelength interval of the measurements, in nm;

$\tau(\lambda)$ is the spectral transmittance of filter material at wavelength λ.

NOTE 1 The colour coordinates (x, y) of the protective filters might be optionally presented on a CIE chromaticity chart.

NOTE 2 There are no requirements for the colour perception of the filters of eye protectors intended for use by ILS equipment patients/clients; these filters may be opaque.

6 Auto darkening filters

Auto darkening filters shall provide the required levels of IR and UV protection specified in Tables 1 and 2 in light and dark states.

In the case of protective filters that exhibit a change of luminous transmittance in response to an exposure to incident optical radiation, the time taken by the eye protector to reach 3x the minimum luminous transmittance ("dark state") shall be determined.

Auto darkening filters powered by mains, batteries or photoelectric cells shall reduce the luminous transmittance (380 nm to 780 nm) to maximum of 30 % if the power supply is disconnected or malfunctions.

The minimum luminous transmittance in the light and dark states of auto darkening filters shall be specified, for the angles of incidence at least between 0° and 30°.

7 Construction of eye protectors

7.1 General

Mirror-finish or metalized finishes on filters or frames shall not be used.

NOTE Secondary reflections from frames or filters of protective eyewear, especially from concave surfaces, might increase the risk of uncontrolled exposure of the users.

7.2 Frames and side shields

Frames and side shields through which exposure to incident optical radiation could occur to the eyes shall give at least the same protection as the filters and shall be designed to prevent the leakage of optical radiation around the edges of protective eyewear.

7.3 Materials

When assessed in accordance with visual inspection, for those parts of the eye protector that come into contact with the skin, materials shall not be used which are known to be likely to cause skin irritation or any adverse effect on health.

Substances recommended for cleaning, maintenance or disinfection shall have no adverse effect on the eye protector and shall be known not to be likely to have any adverse effect upon the wearer, when applied in accordance with the eye protector manufacturer's instructions.

Information claiming that the product is innocuous shall be examined.

The following are examples of documents that shall be provided for examination:

— materials specifications;

— safety data sheets relating to the materials;

— information relating to the suitability of the materials for use with food, in medical devices, or other relevant applications;

— information relating to toxicological, allergenic, carcinogenic, toxic to reproduction, or mutagenic investigations on the materials.

If the eye or face protector incorporates metallic components which are in direct and prolonged contact with the user during wear, these components shall optionally be tested for nickel release according to ISO/TS 24348. The nickel release shall be less than 0,5 µg/cm^2/week.

NOTE National regulations may require assessment of nickel release to be mandatory.

When examined by a person with a visual acuity of at least 1,0 (6/6 or 20/20), when viewing without magnification but wearing the appropriate correction, if any, for near vision, there shall be no sharp edges, roughness or projection on any parts of the eye protector which are in contact, or potential contact, with the wearer, when the eye protector is worn, such as is likely to cause injury to the wearer.

7.4 Adjustment

Any part of the eye protector that can be adjusted, or removed by the wearer for the purpose of replacement (in accordance with the eye protector manufacturer's instructions), shall be so designed and manufactured as to facilitate adjustment, removal and attachment without the use of tools.

Any adjustment system incorporated within the eye protector shall be so designed and manufactured as not to become incorrectly adjusted without the wearer's knowledge under the foreseeable conditions of use.

Test by visual inspection, and adjustment/donning in accordance with the manufacturer's instructions, followed by a minimum of 5 min of wear while seated. During this wear period, the head shall be moved side to side and up/down 3 times per minute.

7.5 Removal of filters

The removal of individual filters from the frame shall only be possible with the use of tools.

If the filters consist of several individual filters (hybrid filters), they shall be assembled in such a way that they cannot be interchanged.

NOTE Hybrid filters should not delaminate after storage, when tested in accordance with Annex G and Annex H.

7.6 Material and surface quality

Except in a marginal area 5 mm wide, filters shall have no material or machining defects within an area of 30 mm diameter around the reference point that may impair vision, e.g. bubbles, scratches, inclusions, dull spots, pitting, mould marks, notches, reinforced areas, specks, beads, water specks, pocking, gas inclusions, splintering, cracks, polishing defects or undulations.

Test according to ISO 12311:2013, 6.2.

7.7 Field of view

Eye protectors intended for use by ILS equipment operators shall have a clear field of view at least ± 40° with respect to the corneal vertex in the vertical and horizontal directions for each eye.

NOTE There are no requirements for the field of view, material and surface defects of the filters of eye protectors intended for use by ILS equipment patients/clients; these filters may be opaque.

7.8 Optical properties

7.8.1 Variation in transmittance

The relative variations of the transmittance around the visual centre(s) shall not exceed ± 10 %.

The relative variations of the luminous transmittance around the visual centre(s) shall not exceed ± 10 %.

The relative variations of the luminous transmittance between left and right eye shall not exceed ± 10 %.

7.8.2 Spherical and astigmatic power

The oculars shall be tested at the reference points in the as worn position according to ISO 12311:2013, 8.1 after cleaning according to the manufacturer's instructions.

The spherical power and astigmatic power shall not exceed the following tolerances.

— Spherical power - Mean value of the optical power values in the two principal meridians [$(D_1 + D_2)/2$ dioptres]: ±0,06.

— Astigmatic power - Absolute difference between the optical power values in the two principal meridians ($|D_1 - D_2|$ dioptres): 0,06.

— Additional requirements for mounted oculars, one-piece and visor types: the maximum difference between the measured spherical powers of the right and left eye shall be 0,12 dioptres.

7.8.3 Local variations in refractive power

The image of the chart used to assess spherical and astigmatic power at of ISO 12311:2013, 8.3.1, shall be clear and sharp.

If during the measurements using the telescope a doubling or other aberration of the image is observed then the oculars shall be tested at the reference point in the as worn position according to ISO 12311:2013, 8.3.

7.8.4 Prismatic deviation of unmounted oculars

The oculars shall be tested at the reference point in the as worn position according to the test method in ISO 12311:2013, 8.1 after cleaning according to the manufacturer's instructions.

The prismatic power shall not exceed 0,12 prism dioptres.

7.8.5 Prismatic power difference for mounted oculars and one-piece protectors

The oculars shall be tested in the as worn position according to ISO 12311:2013, 8.2 after cleaning according to the manufacturer's instructions.

Use the diaphragm LB2 with Xb = (32,0±0,2) mm. Alternatively a diaphragm with a different Xb may be used if specified by the manufacturer.

The prismatic power difference shall not exceed the values in Table 3.

Table 3 — Maximum permitted prismatic power differences for mounted oculars and one piece protectors

Horizontal		Vertical
Base out prism dioptres	Base in prism dioptres	Prism dioptres
0,75	0,25	0,25

7.8.6 Narrow angle scattering (diffusion of light)

The value of the reduced luminance factor (diffusion) shall not exceed 1,0 $cd \cdot m^{-2} \cdot lx^{-1}$ when measured according to Annex E after cleaning according to the manufacturer's instructions.

7.9 Resistance to ignition

All parts of eye protectors that are exposed when worn shall be tested in accordance with Annex F and shall not ignite or continue to glow after removal of the heated rod.

7.10 Resistance to ageing by UV radiation

When tested in accordance with Annex G, the relative change of luminous transmittance shall not be greater than ± 10 % and the value of the reduced luminous factor shall not exceed 0,5 $cd \cdot m^{-2} \cdot lx^{-1}$.

7.11 Resistance to thermal ageing

When tested in accordance with Annex H, eye protectors shall not show apparent deformation.

8 Labelling

Each ILS eye protector shall be clearly and permanently marked to indicate the following:

a) model number;

b) manufacturer's identification;

c) eyewear classified according to 4.2 and/or 4.3 shall be marked F-# and/or B-#, respectively, where # = 1 to 6;