INTERNATIONAL STANDARD

ISO 12609-1

Second edition
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Eye and face 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 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 94 *Personal safety — Personal protective equipment*, Subcommittee SC 6, *Eye and face protection,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 85, *Eye protective equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 12609-1:2013) which has been technically revised.

The main changes compared to the previous edition are as follows:

— Alignment to ISO 16321 series and ISO 18526 series.

A list of all parts in the ISO 12609 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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

Part 1: Specification for products

1 Scope

This document specifies general requirements for operators' eye protectors for intense light source (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 document is applicable to devices intended for patient protection during ILS procedures, except for treatment in the periorbital area. For guidance on patient eye protection during ILS procedures, see ISO/TR 22463.

For guidance on the use and selection of ILS eye protectors, see ISO 12609-2.

This document does not apply to:

— laser protectors, for which ISO 19818-1 applies;

— protectors for medically prescribed applications (not occupational), e.g. eye protection for severe dry eye, tints prescribed for medical conditions;

— protectors specifically intended for protection against only solar radiation and used in non-occupational environments for which the ISO 12312 (all parts) applies;

— protectors used with tanning equipment;

— protectors intended to protect against ionizing radiation, e.g. X-rays, for which IEC 61331-3 applies.

2 Normative references

The following documents 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 applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4007, *Personal protective equipment — Eye and face protection — Vocabulary*

ISO 18526-1:2020, *Eye and face protection — Test methods — Part 1: Geometrical optical properties*

ISO 18526-2:2020, *Eye and face protection — Test methods — Part 2: Physical optical properties*

ISO 18526-3:2020, *Eye and face protection — Test methods — Part 3: Physical and mechanical properties*

ISO 18526-4, *Eye and face protection — Test methods — Part 4: Headforms*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4007 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
intense light source
ILS
device incorporating one or more non-laser, pulsed or continuous, sources of optical radiation in the wavelength range 250 nm to 3 000 nm and intended to cause biological effects in humans and animals

3.2
opaque patient eye protector
protector made from a medium with spectral transmittance no more than 0,01 % in the waveband 250 nm to 3 000 nm

Note 1 to entry: This can be made of metal or intensely pigmented material.

4 Classes of ILS eye protectors

There are three classes of ILS eye protector

a) F-scale eye protector where the scale number is determined by its luminous transmittance for CIE standard illuminant D65,

b) B-scale protector where the scale number is determined by its blue-light transmittance, and

c) Opaque eye protectors, for patient use only.

5 General requirements for ILS eye protectors

5.1 Ambient temperatures

ILS eye protectors described in this document are intended for use at normal ambient temperatures, (23 ± 5) °C.

5.2 Physiological compatibility

ILS eye protectors shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the health or safety of the wearer. The risks posed by substances leaking or evaporating from the ILS eye protector that can come into prolonged contact with the wearer shall be reduced by the manufacturer to within the limits of any applicable regulatory requirement.

Special attention shall be given to substances that are allergenic, carcinogenic, mutagenic or toxic to reproduction.

NOTE 1 Excessive pressure due to a poor fit on the head, chemical irritation and allergy are known to produce reactions. Rare or idiosyncratic reactions to any material are known to occur and the individual wearer is well advised to avoid those types of frame materials.

Substances recommended for cleaning, maintenance or disinfection shall be known to be unlikely to have any adverse effect upon the wearer when applied in accordance with the instructions given in the information to be supplied by the manufacturer.

Manufacturers/suppliers shall perform an appropriate risk analysis on potentially harmful substances contained in the ILS eye protector such that, when the ILS eye protector is used under the intended conditions and for the purposes intended, the health and safety of the wearer shall not be compromised.