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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 (ISO
12609-1:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN ISO 12609-1:2025 sisaldab Euroopa standardi EN ISO 12609-1:2025 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 04.06.2025.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN ISO 12609-1:2025 consists of the English text of the European standard EN ISO 12609-1:2025.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 04.06.2025.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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ICS 13.340.20

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EUROPEAN STANDARD

EN ISO 12609-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2025

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English Version

Eye and face protection against intense light sources used
on humans and animals for cosmetic and medical
applications - Part 1: Specification for products (ISO
12609-1:2021)

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 (ISO
12609-1:2021)

Augen- und Gesichtsschutz gegen intensive
Lichtquellen, die für kosmetische und medizinische
Anwendungen an Menschen und Tieren eingesetzt
werden - Teil 1: Produktanforderungen (ISO 12609-
1:2021)

This European Standard was approved by CEN on 17 October 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 12609-1:2025) has been prepared by Technical Committee ISO/TC 94 "Personal safety - Personal protective equipment" in collaboration with Technical Committee CEN/TC 85 "Eye protective equipment" the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2025, and conflicting national standards shall be withdrawn at the latest by December 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 12609-1:2021 has been approved by CEN as EN ISO 12609-1:2025 without any modification.

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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.