SLOVENSKI STANDARD
oSIST prEN ISO 16321-4:2023

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Zaščita za oči in obraz za poklicno uporabo - 4. del: Dodatne zahteve za zaščito pred biološkimi nevarnostmi (ISO/DIS 16321-4:2023)

Eye and face protection for occupational use - Part 4: Additional requirements for protection against biological hazards (ISO/DIS 16321-4:2023)

Augen- und Gesichtsschutz für berufliche Anwendungen - Teil 4:Zusätzliche Anforderungen zum Schutz vor biologischen Gefahren (ISO/DIS 16321-4:2023)

Protection des yeux et du visage à usage professionnel - Partie 4: Exigences complémentaires pour la protection contre les risques biologiques (ISO/DIS 16321-4:2023)

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Eye and face protection for occupational use —

Part 4:
Additional requirements for protection against biological hazards

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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*.

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.

Introduction

This Standard has been developed in the context of the COVID 19 pandemic, with significant learnings relating to infection control procedures accelerated in 2020. An informative Annex is included in this standard which provides information intended to guide end users and organisations about the appropriate PPE specifically relating to eye or eye and face protection. The guidance is based on knowledge of best-practice and may be used to help define and develop procedures and practice, incorporating the use of products complying with this standard.

The requirements and principles apply independently of the method of manufacture.

Eye and face protection for occupational use —

Part 4: Additional requirements for protection against biological hazards

1 Scope

This document specifies minimum requirements for protectors designed to provide protection for the eyes or eyes and face from biological hazards, such as human or other animal bodily fluids and microorganisms, including viruses and other particulates, that may deposit onto the face or eyes.

This document specifies requirements for both single-use (disposable) and re-usable (disinfectable) products or components.

This document applies to all afocal (plano) and prescription lensed protectors and their components.

This document does not apply to:

— protectors intended for protection from specific hazards, e.g., impact from high speed particles, harmful artificial optical radiation, dusts, molten metals, heat, flame, hot solids, harmful gases, vapours (refer to ISO 16321 parts 1 to 3);

— protectors specifically for sports (refer to ISO 18527 series);

— protectors for lasers (refer to ISO 19818-1);

— respiratory protection against aerosols (refer to ISO 16900 series);

Note 1 Guidance relating to the specific selection, use and maintenance is provided in Annex A.

Note 2 Where eye and face protection is incorporated in protective equipment, such as a hood, full face respirators, PAPR hoods and headtops, the relevant requirements of this standard apply to the components providing eye and face protection.

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

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

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

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

ISO 16321-1, *Eye and face protection for occupational use — Part 1: General requirements*

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

ISO 21987, *Ophthalmic optics — Mounted spectacle lenses*

ISO 15190:2020, *Medical laboratories — Requirements for safety*

CAS 518-47-8

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 https://www.electropedia.org/

3.1
aerosol (aerosolized)
<biological> colloidal suspension of liquid or solid particles dispersed in a gas (usually air), smoke or fog

[SOURCE: ISO 15190: 2020, 3.2, modified – put in the singular and domain <biological> was added]

3.2
airborne
any biological material that is in the air (suspended or travelling)

Note 1 to entry: The biological material can include splashes, spurts, sprays, aerosols and droplets

3.3
airborne transmission
spread of an infectious agent caused by the dissemination of droplet nuclei (aerosols) that remain infectious when suspended in the air over long distances and time

3.4
biological hazard
biological substance(s) that pose(s) a threat to the health of living organisms, primarily that of humans.

Note 1 to entry: This can include medical waste or samples of a microorganism, virus, or toxin (from a biological source) that can affect human health.

3.5
cleaning
process to remove any type of contamination,

Note 1 to entry: The contamination can be visible or not

3.6
decontamination
procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects

3.7
disinfection
process to reduce the number of *microorganisms* (3.9), but not usually of bacterial spores, without necessarily killing or removing all organisms

[SOURCE: ISO 15190: 2020; 3.9]

3.8
droplet
very small drop of liquid

Note 1 to entry: A small drop, such as a particle of moisture discharged from the mouth during coughing, sneezing, speaking or released by agitation or spillage of a liquid source.

Note 2 to entry: These can transmit pathogens and cause infection by dispersion into the air.

Note 3 to entry: Particles intermediate in size between drops and aerosol can contain infectious microorganisms and tend to quickly settle from the air such that risk of disease transmission is usually limited to persons in close proximity to the droplet source.

Note 4 to entry: Particle size impacts on the amount of time it will remain in the air and this can potentially change whilst suspended in air (due to evaporation)

3.9
microorganisms
microscopic organisms including protozoa and other parasites, fungi, archaea, bacteria, unicellular algae, viruses and viroids

3.10
infectious microorganism
microorganism (3.9) capable of invading a susceptible host and multiplying in it

Note 1 to entry: Infectious microorganisms can but need not, cause a disease

3.11
pathogen
an infectious organism, usually microscopic, capable of causing disease in a host

3.12
re-usable
product intended to be cleaned and disinfected for multiple use

3.13
single use
use by a single person within a specified time frame or exposure situation

Note 1 to entry: Single use products are generally not appropriate for disinfection

3.14
splash
liquid scattered through the air or onto something

3.15
spray
very small drops of liquid carried in the air

3.16
spurt
sudden fast stream of liquid

EXAMPLE cough of mucus, leak from laboratory process, spurt from blood vessel in surgical/paramedical settings

3.17
sterile
free from viable microorganisms

Note 1 to entry: In practice, no such statement regarding the absence of microorganisms can be proven.

3.18
sterilization
validated process used to render a product free from viable microorganisms

Note 1 to entry: The number of microorganisms that survive a sterilization process can be expressed in terms of probability. While the probability may be reduced to a very low number, it can never be reduced to zero.

[SOURCE: ISO/TS 11139:2006, 2.47 – modified by addition of note to entry.]

3.19
Mean transmittance in the range 450 to 650 nm, $\tau_{m,450\text{-}650}$

$$\tau_{m,450\text{-}650} = \left(\sum_{450\ nm}^{650\ nm} \tau(\lambda)\ d\lambda \right) \Big/ \left(\frac{200}{d\lambda} + 1 \right)$$

where

$\tau(\lambda)$ is the spectral transmittance at wavelength λ and

$d\lambda$ is the wavelength interval of the measurements

4 General requirements for protectors

4.1 General

Only those requirements that are different from or supplement the ISO 16321-1 specifications are given in this document.

The following requirements from ISO 16321-1: 2021 shall be met:

— 4.2 Physiological compatibility

— 4.3 Construction and adjustment

— 4.5 Headform(s)

— 4.6 Mandatory and optional requirements

— 5.1 Field of view

— 5.2 Refractive power and prismatic power for plano lenses

— 5.3 Mounted prescription lenses

— 5.4 Single-vision ready-to-wear near-vision lenses (lenses with positive spherical power)

— 6.5 Scattered light

— 6.7 Anti-reflective coated lenses, optional

— 7.2 Headbands and harnesses

— 7.3 Quality of material and surface of mounted and unmounted lenses, visors and filters

— 7.8 Resistance to ignition

— 7.13 Resistance to fogging of lenses or filters (optional).

The additional requirements given in this document shall be met.

4.2 Ambient temperature

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