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# Eye and face protection —

## Part 4: Protection against biological hazards

*Protection des yeux et du visage —*

*Partie 4: Protection contre les risques biologiques*

Reference number
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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 document 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).

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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).

A list of all parts in the ISO 16321 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.

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# Introduction

This document has been developed in the context of the COVID 19 pandemic, with significant learnings relating to infection control procedures accelerated in 2020. When developing this document, there were a number of lightweight protectors being used that do not conform with the requirements of ISO 16321-1, in particular the mechanical requirements. As these lightweight protectors provide protection only against biological hazards, a separate standard was created with requirements relating to biological hazards and no requirements relating to mechanical hazards (except that the lens or face shield should not break under minor impact to create a secondary hazard). In addition, the spray and spurt tests were adopted as they are more representative of the biological hazards associated with human and animal biological fluids, than the resistance to splash or streams of liquids methods in ISO 16321-1.

Annex A provides information intended to guide end users and organizations about the appropriate personal protective equipment (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 conforming with this document.

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

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# Eye and face protection —

# Part 4: Protection against biological hazards

## 1 Scope

This document specifies minimum requirements for light-weight protectors designed to provide protection for the eyes or eyes and face from biological hazards, such as pathogenic micro-organisms in human or other animal bodily fluids that can deposit onto the face or eyes.

NOTE 1 Typical scenarios for use include healthcare, retail and transport settings.

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 cover the respiratory equipment required for protection against aerosols, which can be used in conjunction with these eye protectors, and for which other standards apply.

This document does not apply to

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

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

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

— respiratory protection against aerosols (refer to ISO/TS 16975-4).

NOTE 2 Guidance related to the specific selection, use and maintenance is provided in Annex A.

NOTE 3 Where eye and face protection is incorporated in protective equipment, such as a hood, full face respirators, powered air purifying respirators (PAPR) hoods and headtops, the relevant requirements of this document 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 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 4007:2018, *Personal protective equipment — Eye and face protection — Vocabulary*

ISO 16321-1:2021, *Eye and face protection for occupational use — Part 1: General requirements*

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*

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ISO 18526-4:2020, *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 terminology 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**
<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

Note 2 to entry: Airborne transmission is the 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

**3.3**
**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.

**3.4**
**cleaning**
act of removing contaminants from protective equipment by mechanical, chemical, thermal, or combined processes

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

Note 2 to entry: Decontamination is a procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects.

[SOURCE: ISO/TR 21808:2024, 3.3, modified — Notes to entry have been added.]

**3.5**
**disinfection**
reduction, by means of chemical agents and/or physical methods, of the number of *microorganisms* (3.7) in the environment, to an acceptable level

Note 1 to entry: Sterile can be defined as free from viable microorganisms**.** In practice, no such statement regarding the absence of microorganisms can be proven.

[SOURCE: ISO/TS 22002-1:2002, 3.9, modified — removed reference to food safety and suitability; Note to entry has been replaced.]

**3.6**
**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.

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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).

**3.7**
**microorganism**
microscopic organisms including protozoa and other parasites, fungi, archaea, bacteria, unicellular algae, viruses and viroids

**3.8**
**pathogen**
infectious agent capable of causing disease in its host

Note 1 to entry: Pathogens include some viruses, bacterium, prions, fungi, viroids, or parasites.

[SOURCE: ISO 15714:2019, 3.1.2]

**3.9**
**re-usable**
product intended to be cleaned and disinfected for multiple use

**3.10**
**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

**3.11**
**splash**
liquid scattered through the air or onto something

**3.12**
**spray**
very small drops of liquid carried in the air

**3.13**
**spurt**
sudden fast stream of liquid

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

**3.14**
**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 11139:2018, 2.277, modified — Note 1 to entry has been revised.]

**3.15**
**mean spectral transmittance in the range 450 nm to 650 nm**
$\tau_{m,450\text{-}650}$
averaged value of the spectral transmittance in the wavelength range from 450 nm to 650 nm

Note 1 to entry: The *mean spectral transmittance in the range 450 nm to 650 nm* is usually expressed as a percentage and calculated from the following formula:

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

where

$\tau(\lambda)$ is the spectral transmittance at wavelength $\lambda$, in percent, and

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

**3.16**
**half mask**
tight-fitting respiratory interface covering the mouth, nose and chin

[SOURCE: ISO 16972:2020, 3.104]

**3.17**
**full face mask**
facepiece which covers the eyes, nose, mouth, and chin and provides adequate sealing on the face of the wearer of a respiratory protective device against the ambient atmosphere

**3.18**
**surgical mask**
**medical mask**
product that covers the wearer's nose and mouth and provides a physical barrier to fluids and particulate materials

Note 1 to entry: These products are not classed as respiratory protection devices (RPD).

[SOURCE: ISO/TS 16975-4:2022, 3.21]

# 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

— 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

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