SLOVENSKI STANDARD
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Naprave za preprečevanje respiratornih okužb za lastno zaščito in zaščito tretjih oseb - 1. del: Zahteve in označevanje

Respiratory infection prevention devices for self- and third-party protection - Part 1: Requirements and marking

Atemwegsinfektionsschutzgeräte für den Selbst- und Fremdschutz - Teil 1: Anforderungen und Kennzeichnung

Dispositifs de prévention des infections respiratoires pour la protection individuelle et de tiers - Partie 1 : Exigences et marquage

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13.340.20 Varovalna oprema za glavo Head protective equipment

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English Version

Respiratory infection prevention devices for self- and third-party protection - Part 1: Requirements, test methods, classification and marking

Dispositifs de prévention des infections respiratoires pour la protection individuelle et de tiers - Partie 1: Exigences, méthodes d'essai, classification et marquage

Atemwegsinfektionsschutzgeräte für den Selbst- und Fremdschutz - Teil1: Anforderungen, Prüfverfahren, Klassifizierung und Kennzeichnung

This draft European Standard is submitted to CEN members for second enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (prEN 18178-1.2:2026) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the second CEN Enquiry.

The EN 18178 series consists of the following parts, under the general title *Respiratory infection prevention devices for self- and third-party protection*:

— *Part 1: Requirements, test methods, classification and markings*

— *Part 3: Sustainability, human factors and rationales*

— *Part 4: Selection and use*

Introduction

A device that protects in both directions of breathing (outward and inward) can be required to reduce infection for example during outbreaks of respiratory infections or similar situations.

This document aims to specify requirements for devices for the prevention of respiratory infections that are harmonized under both the MDR and the Personal Protective Equipment (PPE) Regulation.

The EN 18178 series of standards is a user- and performance-oriented series of standards.

A product that meets all the requirements of this document, regardless of its design, can be used as a respiratory infection prevention device (RIPD) and offers protection against infective agents at the level described in the classification.

Requirements, test methods, classification and marking are described in this document.

The classification is part of the mandatory marking. As the intended users of the standardized devices are the general population, the performance class is also intended to be indicated by easily recognizable and clearly interpretable information. This will enable the safe and appropriate selection of a product.

Supplementary parts of the EN 18178 series are CEN/TS 18178-3 and CEN/TS 18178-4.

CEN/TS 18178-3 contains references and descriptions of the ‘human factors’ used to determine the limit values in EN 18178-1. In addition, CEN/TS 18178-3 takes into account aspects of environmental compatibility and sustainability.

CEN/TS 18178-4 provides a procedure for the ‘selection and use’ of appropriate devices. This is based on factors such as infectivity, the environment of use, the activities and physical capabilities of the wearers on the one hand, and the classification on the other.

1 Scope

This document specifies minimum performance requirements, test methods, classification as well as marking for respiratory infection prevention devices (RIPDs).

RIPDs are intended to reduce the emission of infective agents from the user's airways into the environment and also reduce exposure to the user from inhalation of infective agents.

RIPDs are intended for use by the general population.

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.

EN 13274-2:2019, *Respiratory protective devices — Methods of test — Part 2: Practical performance tests*

EN 14683:2025, *Medical face masks — Requirements and test methods*

EN ISO 16972:2020, *Respiratory protective devices — Vocabulary and graphical symbols (ISO 16972:2020)*

EN ISO 10993-1:2026, *Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process (ISO 10993-1:2025)*

EN ISO 10993-23:2021, *Biological evaluation of medical devices — Part 23: Tests for irritation (ISO 10993-23:2021)*

EN IEC 60812:2018, *Failure modes and effects analysis (FMEA and FMECA)*

ISO 16900-1:2019, *Respiratory protective devices — Methods of test and test equipment — Part 1: Determination of inward leakage*

ISO 16900-2:2017, *Respiratory protective devices — Methods of test and test equipment — Part 2: Determination of breathing resistance*

ISO 16900-5:2016,[1] *Respiratory protective devices — Methods of test and test equipment — Part 5: Breathing machine, metabolic simulator, RPD headforms and torso, tools and verification tools*

ISO 16900-7:2020, *Respiratory protective devices — Methods of test and test equipment — Part 7: Practical performance test methods*

ISO 16900-9:2015, *Respiratory protective devices — Methods of test and test equipment — Part 9: Determination of carbon dioxide content of the inhaled gas*

ISO 16900-10:2015, *Respiratory protective devices — Methods of test and test equipment — Part 10: Resistance to ignition, flame, radiant heat and heat*

ISO 16900-11:2025, *Respiratory protective devices — Methods of test and test equipment — Part 11: Determination of field of vision*

ISO 16900-12:2016, *Respiratory protective devices — Methods of test and test equipment — Part 12: Determination of volume-averaged work of breathing and peak respiratory pressures*

[1] This document is impacted by an amendment ISO 16900-5:2016/Amd 1:2018.