SLOVENSKI STANDARD
SIST EN 149:2001+A1:2009

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Oprema za varovanje dihal - Polobrazne maske za zaġļ ito pred delci - Zahteve, preskuġanje, oznaļ evanje

Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Atemschutzgeräte - Filtrierende Halbmasken zum Schutz gegen Partikeln - Anforderungen, Prüfung, Kennzeichnung

Appareils de protection respiratoire - Demi-masques filtrants contre les particules - Exigences, essais, marquage

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13.340.30	Varovalne dihalne naprave	Respiratory protective devices

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EUROPEAN STANDARD

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English Version

Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Appareils de protection respiratoire - Demi-masques filtrants contre les particules - Exigences, essais, marquage

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This European Standard was approved by CEN on 8 March 2001 and includes Corrigendum 1 issued by CEN on 24 July 2002 and Amendment 1 approved by CEN on 26 March 2009.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Contents

Foreword

This document (EN 149:2001+A1:2009) has been prepared by Technical Committee CEN/TC 79 "Respiratory protective devices", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by November 2009.

This European Standard supersedes [A1⟩ EN 149:2001 ⟨A1].

This European Standard was approved by CEN on 8 March 2001 and includes Corrigendum 1 issued by CEN on 24 July 2002 and Amendment 1 approved by CEN on 26 March 2009.

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A1⟩ ⟨A1].

The modifications of the related CEN Corrigendum have been implemented at the appropriate places in the text and are indicated by the tags [AC⟩ ⟨AC].

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

Annex A is informative.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

A given respiratory protective device can only be approved when the individual components satisfy the requirements of the test specification which may be a complete standard or part of a standard, and practical performance tests have been carried out successfully on complete apparatus where specified in the appropriate standard. If for any reason a complete apparatus is not tested then simulation of the apparatus is permitted provided the respiratory characteristics and weight distribution are similar to those of the complete apparatus.

1 Scope

This European Standard specifies minimum requirements for filtering half masks as respiratory protective devices to protect against particles except for escape purposes.

Laboratory and practical performance tests are included for the assessment of compliance with the requirements.

2 Normative references

[A1] The following referenced documents are indispensable for the application 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. [A1]

EN 132, *Respiratory protective devices - Definitions of terms and pictograms*

EN 134, *Respiratory protective devices - Nomenclature of components*

EN 143, *Respiratory protective devices - Particle filters - Requirements, testing, marking*

[A1] EN 13274-7, *Respiratory protective devices – Methods of test – Part 7: Determination of particle filter penetration* [A1]

ISO 6941, *Textile fabrics - Burning behaviour - Measurement of flame spread properties of vertically oriented specimens*

3 Terms and definitions

For the purposes of this European Standard the definitions given in EN 132 and the nomenclature given in EN 134 apply [A1] together with the following:

3.1
re-useable particle filtering half mask
particle filtering half mask intended to be used for more than a single shift [A1]

4 Description

A particle filtering half mask covers the nose and mouth and the chin and may have inhalation and/or exhalation valve(s). The half mask consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device.

It is intended to provide adequate sealing on the face of the wearer against the ambient atmosphere, when the skin is dry or moist and when the head is moved.

Air enters the particle filtering half mask and passes directly to the nose and mouth area of the facepiece or, via an inhalation valve(s) if fitted. The exhaled air flows through the filter material and/or an exhalation valve (if fitted) directly to the ambient atmosphere.

These devices are designed to protect against both solid and liquid aerosols.

5 Classification

Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:

FFP1, FFP2 and FFP3.

The protection provided by an FFP2 - or FFP3 - device includes that provided by the device of lower class or classes.

[A1] In addition, particle filtering half masks are classified as single shift use only or as re-usable (more than one shift). [A1]

6 Designation

Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner:

[A1] Particle filtering half mask EN 149, year of publication, classification, option (where "D" is an option for a non re-useable particle filtering half mask and mandatory for re-useable particle filtering half mask). [A1]

[A1] EXAMPLE Particle filtering half mask EN 149:2001 FFP1 NR D [A1]

7 Requirements

7.1 General

In all tests all test samples shall meet the requirements.

7.2 Nominal values and tolerances

Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of ± 5 %. Unless otherwise specified, the ambient temperature for testing shall be (16 - 32) °C, and the temperature limits shall be subject to an accuracy of ± 1 °C.

7.3 Visual inspection

The visual inspection shall also include the marking and the information supplied by the manufacturer.

7.4 Packaging

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

Testing shall be done in accordance with 8.2.

7.5 Material

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

Three particle filtering half masks shall be tested.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Testing shall be done in accordance with 8.2.

7.6 Cleaning and disinfecting

[A1] If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. [A1]

Testing shall be done in accordance with 8.4 and 8.5.

[A1] With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.

Testing shall be done in accordance with 8.11. [A1]

7.7 Practical performance

The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.

Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections.

Testing shall be done in accordance with 8.4.

7.8 Finish of parts

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Testing shall be done in accordance with 8.2.

7.9 Leakage

7.9.1 Total inward leakage

The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected.

The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than

25 % for FFP1

11 % for FFP2

5 % for FFP3

and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than

22 % for FFP1

8 % for FFP2

2 % for FFP3.

Testing shall be done in accordance with 8.5.

7.9.2 Penetration of filter material

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

Table 1 — Penetration of filter material

Classification	[A1] Maximum penetration of test aerosol [A1]	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

[A1] A total of 9 samples of particle filtering half masks shall be tested for each aerosol.

Testing in accordance with 8.11 using the Penetration test according to EN 13274-7, shall be performed on:

- 3 samples as received;
- 3 samples after the simulated wearing treatment described in 8.3.1.

Testing in accordance with 8.11 using the Exposure test with a specified mass of test aerosol of 120 mg, and for particle filtering devices claimed to be re-usable additionally the Storage test, according to EN 13274-7, shall be performed:

- for non-re-usable devices on:

  - 3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2.

- for re-usable devices on:

  - 3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2. and followed by one cleaning and disinfecting cycle according to the manufacturer's instruction. [A1]

7.10 Compatibility with skin

Materials that may come into contact with the wearer’s skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Testing shall be done in accordance with 8.4 and 8.5.

7.11 Flammability

The material used shall not present a danger for the wearer and shall not be of highly flammable nature.

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

The particle filtering half mask does not have to be usable after the test.

Testing shall be done in accordance with 8.6.

7.12 Carbon dioxide content of the inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).

Testing shall be done in accordance with 8.7.

7.13 Head harness

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Testing shall be done in accordance with 8.4 and 8.5.

7.14 Field of vision

The field of vision is acceptable if determined so in practical performance tests.

Testing shall be done in accordance with 8.4.

7.15 Exhalation valve(s)

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

Testing shall be done in accordance with 8.2 and 8.9.1.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

Testing shall be done in accordance with 8.2.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

Testing shall be done in accordance with 8.3.4.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

Testing shall be done in accordance with 8.8.

7.16 Breathing resistance

The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.

Testing shall be done in accordance with 8.9.

Table 2 — Breathing resistance

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

7.17 Clogging

7.17.1 General

[A1] For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory. [A1]

Devices designed to be resistant to clogging, shown by a slow increase of breathing resistance when loaded with dust, shall be subjected to the treatment described in 8.10.

The specified breathing resistances shall not be exceeded before the required dust load of 833 mg•h/m^3 is reached.

7.17.2 Breathing resistance

7.17.2.1 Valved particle filtering half masks

After clogging the inhalation resistances shall not exceed

— FFP1: 4 mbar

— FFP2: 5 mbar

— FFP3: 7 mbar

at 95 l/min continuous flow;

The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Testing shall be done in accordance with 8.9.

7.17.2.2 Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed

— FFP1: 3 mbar

— FFP2: 4 mbar

— FFP3: 5 mbar

at 95 l/min continuous flow.

Testing shall be done in accordance with 8.9.

7.17.3 A1 Penetration of filter material

All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.

Testing shall be done in accordance with 8.11 using EN 13274-7 A1

7.18 Demountable parts

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.

Testing shall be done in accordance with 8.2.

8 Testing

8.1 General

If no special measuring devices and methods are specified, commonly used devices and methods shall be used.

NOTE For a summary of testing, see Table 4.

Before performing tests involving human subjects account should be taken of any national regulations concerning the medical history, examination or supervision of the test subjects.

8.2 Visual inspection

The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.

8.3 Conditioning

8.3.1 Simulated wearing treatment

Conditioning by simulated wearing treatment shall be carried out by the following process.

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask is mounted on a Sheffield dummy head. For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head. The air shall be saturated at (37 ± 2) °C at the mouth of the dummy head. In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be inclined so that the water runs away from the mouth and is collected in a trap.

The breathing machine is brought into operation, the saturator switched on and the apparatus allowed to stabilize. The particle filtering half mask under test shall then be mounted on the dummy head. During the test time at approximately 20 min intervals the particle filtering half mask shall be completely removed from the dummy head and refitted such that during the test period it is fitted ten times to the dummy head.

8.3.2 Temperature conditioning

Expose the particle filtering half masks to the following thermal cycle:

a) for 24 h to a dry atmosphere of (70 ± 3) °C;