SLOVENSKI STANDARD
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Dihalne cevke za uporabo z anestezijskimi aparati in ventilatorji

Breathing tubes intended for use with anaesthetic apparatus and ventilators

Atemschläuche zur Verwendung mit Anästhesie- und Beatmungsgeräten

Tubes (tuyaux) respiratoires destinés à être utilisés avec des appareils d'anesthésie et des ventilateurs

Ta slovenski standard je istoveten z: **EN 12342:1998+A1:2009**

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Foreword

This document (EN 12342:1998+A1:2009) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document includes Amendment 1, approved by CEN on 2009-07-30.

This document supersedes EN 12342:1998.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1〉 〈A1▐.

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.

This European Standard is based on the reference standard ISO 5367 "Breathing tubes intended for use with anaesthetic apparatus and ventilators". It differs from ISO 5367 primarily in that all sizes of breathing tubes are included and that each tube is required to be marked with the rated flow that the manufacturer claims can be achieved without exceeding specified limits for resistance.

Annexes A, B, C, D, E and F are normative. Annexes G, H and ZA are for information only.

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 United Kingdom.

Introduction

This European Standard is one of a package dealing with anaesthetic and respiratory equipment. It is primarily concerned with basic requirements for breathing tubes, including those breathing tubes used with 8,5 mm connectors. Breathing tubes are characterised by the rated flow that a manufacturer claims can be achieved without exceeding specified limits for resistance. The requirements also include means of connection and several methods of test, some of which have not been included in previous International Standards.

Recommendations for materials and design are given in annex G.

1 Scope

This European Standard specifies the basic requirements for breathing tubes and breathing tubing supplied to be cut to length, intended for use with anaesthetic apparatus and ventilators, humidifiers and nebulizers. It also applies to breathing tubes and Y-pieces supplied already assembled and to those supplied as components and assembled in accordance with the manufacturers' instructions.

Provision is made for breathing tubes having ends incorporating adaptors with conical connectors (assembled ends) or with plain ends (either cylindrical or tapered).

Breathing tubes for special purposes, such as those used with ventilators having special compliance requirements and coaxial lumen tubes, are outside the scope of this European Standard.

Unless specified otherwise, the requirements of this European Standard apply equally to breathing tubes intended by the manufacturer for single use and those intended for re-use.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 556:1994, *Sterilization of medical devices – Requirement for medical devices to be labelled 'Sterile'*

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized – Part 1: General requirements and test methods*

EN 980, *Graphical symbols for use in the labelling of medical devices*

EN 1281-1, *Anaesthetic and respiratory equipment – conical connectors – Part 1: Cones and sockets*

EN 30993-1, *Biological evaluation of medical devices – Part 1: Guidance on selection of tests (ISO 10993-1:1992 + Technical Corrigendum 1:1992)*

EN 60601-1:1990, *Medical electrical equipment – Part 1: General requirements for safety (IEC 601-1:1988)*

ISO 468, *Surface roughness – Parameters, their values and general rules for specifying requirements*

3 Definitions

For the purposes of this European Standard, the following definitions apply:

3.1
APL valve; adjustable pressure limiting valve; pop-off valve
pressure limiting valve which releases gas over an adjustable range of pressures [EN ISO 4135:1996]

3.2
breathing tube
non-rigid tube used to convey gases and/or vapours between an anaesthetic machine and/or some ventilators, and a patient [EN ISO 4135:1996]

3.3
adaptor
specialized connector to establish functional continuity between otherwise disparate or incompatible components, one end of which is intended to be inserted into the end of a breathing tube, the other end having a conical connector complying with EN 1281-1

3.4
assembled end
end of a breathing tube incorporating an adaptor

3.5
plain end
end of a breathing tube designed to fit directly over a male conical connector complying with EN 1281-1

3.6
patient end
that end of the breathing tube which is intended to be connected to the Y-piece or other appropriate component near the patient

3.7
machine end
that end of the breathing tube which is intended to be connected to the anaesthetic workstation, ventilator or other breathing attachment furthest from the patient

3.8
antistatic
property of breathing tubes and any integrally attached components with electrical conductivity satisfying specified limits under the test conditions

3.9
compliance
volume added per unit pressure increase when gas is added to an enclosed space, expressed at the temperature and humidity of that enclosed space and at an ambient atmospheric pressure [EN ISO 4135:1996]

3.10
patient connection port
that opening at the patient end of a breathing system intended for connection to a tracheal or tracheostomy tube connector or adaptor, a face mask or a face mask angle piece [5.2.2 of EN ISO 4135:1996]

3.11
3-way breathing system connector; T- or Y-piece
3-way tubular connector for use within a breathing system with a patient connection port and two ports for connection to the breathing system [EN ISO 4135:1996]

3.12
swivel 3-way breathing connector; swivel y-piece
specialised 3-way connector which allows variation in the position of its three ports relative to each other [EN ISO 4135:1996]

3.13
rated flow
flow that the manufacturer claims results in an increase in pressure of not more than that specified in **7.1** or **7.2**, as appropriate

4 Materials

Breathing tubes, in their ready-for-use state after any preparation recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in EN 30993-1.

〚A1〛 If phthalates are incorporated in parts of the medical devices coming directly or indirectly into contact with the patient the medical device shall be labelled accordingly.

NOTE Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction. 〚A1〛

5 Design

Breathing tubes, whether of corrugated constructions or otherwise, shall have plain ends (cylindrical or tapered) and/or assembled ends incorporating 22 mm, 15 mm or 8,5 mm conical connectors complying with EN 1281-1.

NOTE 1 A loop for suspending the tube can be provided near one of the ends.

NOTE 2 The ends of breathing tubes can be constructed to engage with the recess at the base of a 22 mm male conical connector.

NOTE 3 Recommendations for materials and design are given in annex G.

6 Length

6.1 The length of breathing tubes shall be designated by their nominal overall length, expressed in metres, when measured in the resting condition (without being held under tension), lying on a horizontal surface. Breathing tubes intended to be extended when used shall be designated by both the unextended and extended lengths.

6.2 The designated length of breathing tubes provided permanently attached to a Y-piece shall include the length of the Y-piece and any assembled ends.

6.3 The actual length shall be within 10 % of the designated length.

7 Resistance to flow

7.1 When a breathing tube supplied ready for use (with assembled ends and Y-piece, if provided) is tested in accordance with Annex A using the rated flow (see 15.2 d) and 15.3 d)), the increase in pressure shall not exceed 0,2 kPa (2,0 cmH_2O).

7.2 When breathing tubing supplied to be cut to length is tested in accordance with annex A using the rated flow (see 15.2 e) and 15.3 e)), the increase in pressure shall not exceed 0,1 kPa (1,0 cmH_2O) per metre length of tubing.

8 Means of connection

8.1 Plain ends of tubes

8.1.1 The axial length of plain ends of breathing tubes, excluding those specified in 8.1.2, when measured in the resting condition, shall be not less than 21 mm for breathing tubes intended to engage with 22 mm conical connectors, not less than 14 mm for breathing tubes intended to engage with 15 mm conical connectors, or not less than 8 mm for breathing tubes intended to engage with 8,5 mm conical connectors.

8.1.2 The axial length of plain ends of breathing tubes that incorporate an internal ridge, intended to engage with the recess at the base of a 22 mm male conical connector as specified in EN 1281-1, shall be not less than 26,5 mm when measured in the resting condition.

8.1.3 When tested as described in annex B, plain ends of breathing tubes shall not become detached from the appropriate male conical connector.

8.2 Adaptor

The end of the adaptor which is not intended for attachment to the breathing tube shall have a 22 mm, 15 mm or 8,5 mm conical connector conforming to EN 1281-1.

8.3 Assembled end

When tested as described in annex C, the adaptor shall not become detached from the tube.

NOTE For the purpose of this requirement, a Y-piece provided permanently attached to a breathing tube is regarded as an adaptor.

8.4 Breathing tubes permanently attached to a Y-piece

If breathing tubes are supplied in pairs permanently attached to a Y-piece, the patient connection port of that Y-piece shall be a 22 mm/15 mm or 15 mm/8,5 mm male/female coaxial conical connector conforming to EN 1281-1.

9 Leakage

9.1 When tested in accordance with annex D, single breathing tubes shall not leak at a rate of more than 25 ml min^{-1}.

9.2 When tested in accordance with annex D, breathing tubes supplied in pairs permanently attached to a non-swivel Y-piece, shall not leak at a rate of more than 50 ml min^{-1}.

9.3 When tested in accordance with annex D, breathing tubes supplied in pairs permanently attached to a swivel Y-piece shall not leak at a rate of more than 75 ml min^{-1}.

NOTE Requirements for leakage from complete breathing systems including those systems incorporating breathing tubes with swivel Y-pieces are specified in EN 740.

10 Increase in flow resistance with bending

When tested in accordance with annex E, the pressure at the rated flow when the breathing tube is suspended over the metal cylinder shall not exceed 150 % of the value obtained with the tube straight.

11 Compliance of breathing tubes

The compliance of breathing tubes at a pressure of 6 kPa (60 cmH_2O) shall not exceed 10 ml kPa^{-1} (1 ml cmH_2O^{-1}) per metre length of tube when tested in accordance with annex F.

12 Information to be supplied by the manufacturer

12.1 The manufacturer shall, when requested, provide information on the maximum recommended safe working temperature of the breathing tube when attached to a heated humidifier.

12.2 Unless the breathing tube is intended and marked as being for single use, the manufacturer shall provide details of recommended methods of cleaning and disinfection or sterilization.

〈A1〉

12.3 The date of issue or the latest revision of the instructions for use shall be given. 〈A1〉

13 Electrical resistance

The electrical resistance of breathing tubes and any integrally attached components made of conductive material that are intended for use with flammable anaesthetics shall conform to the requirements for prevention of electrostatic charges specified in sub-clause 39.3b) of EN 60601-1:1990.

14 Requirements for breathing tubes supplied sterile

14.1 Sterility assurance

Breathing tubes supplied and marked as 'STERILE' shall satisfy the requirements of 4.1 of EN 556:1994 for the assurance of sterility needed to make the claim of being sterile.

14.2 Packaging of breathing tubes supplied sterile

14.2.1 Breathing tubes supplied and marked 'STERILE' shall be contained in an individual pack.

14.2.2 The pack shall serve as an effective barrier to the penetration of micro-organisms and particulate matter in accordance with EN 868-1.

14.2.3 The pack shall permit the aseptic extraction of the contents and shall not permit re-closure without showing that it has been opened.

〈A1〉

14.2.4 For single use devices the manufacturer shall disclose in the instructions for use or upon request the risks associated with reuse. 〈A1〉