Hingamistorud, mis on ette nähtud kasutamiseks koos anesteesiaaparaatidega ja ventilaatoritega KONSOLIDEERITUD TEKST

Breathing tubes intended for use with anaesthetic apparatus and ventilators CONSOLIDATED TEXT

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12342:1999+A1:2009 sisaldab Euroopa standardi EN 12342:1998+A1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 12342:1999+A1:2009 consists of the English text of the European standard EN 12342:1998+A1:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.10.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.10.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 09.09.2009.	Date of Availability of the European standard text 09.09.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 12342:1998+A1

September 2009

ICS 11.040.10

Supersedes EN 12342:1998

English Version

Breathing tubes intended for use with anaesthetic apparatus and ventilators

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

Atemschläuche zur Verwendung mit Anästhesie- und Beatmungsgeräten

This European Standard was approved by CEN on 30 May 1998 and includes Amendment 1 approved by CEN on 30 July 2009.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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Ref. No. EN 12342:1998+A1:2009: E

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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]