Respiratoorse teraapia seadmed. Osa 2: Torustik ja toruliitmikud

Respiratory therapy equipment - Part 2: Tubing and connectors

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 13544-2:2002+A1:2010 sisaldab Euroopa standardi EN 13544-2:2002+A1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 13544-2:2002+A1:2010 consists of the English text of the European standard EN 13544-2:2002+A1:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.04.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.04.2010 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.

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English Version

Respiratory therapy equipment - Part 2: Tubing and connectors

Equipement de thérapie respiratoire - Partie 2: Tubes et raccords

Atemtherapiegeräte - Teil 2: Schlauchsysteme und Verbindungsstücke

This European Standard was approved by CEN on 1 August 2002 and includes Amendment 1 approved by CEN on 30 July 2009.

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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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Foreword

This document (EN13544-2:2002+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of an identical text or by endorsement, at the latest by March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.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 13544-2:2002.

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).

Annexes A and B are normative. Annex C is informative.

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

EN 13544 consists of the following parts, under the general title Respiratory therapy equipment.

Part 1: Nebulizing systems and their components

Part 2: Tubing and connectors

Part 3: Air entrainment devices

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.

1 Scope

This part of EN 13544 specifies requirements for tubing to be used with equipment for the therapeutic administration of respirable gases in domiciliary, ambulance and hospital practice including the interface to the equipment i.e. nipples and screw threaded connectors. This tubing is mainly used with oxygen, air or mixtures of these gases.

The interface specifications are given to ensure interchangeability of respiratory therapy equipment thereby enabling patients to receive continuous treatment in all these clinical situations.

Weight-bearing screw-threaded connectors are specified for use at the outlet of e.g. flowmeters to which devices such as humidifiers or nebulizers can be attached.

NOTE This standard does not specify the devices where these connectors have to be used. It is expected that specific device standards will specify the devices where these connectors are going to the used e.g. EN ISO 10651-4, EN 738-1 and EN 13220.

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 (including amendments).

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

3 Nipples

3.1 Dimensions

The dimensions of nipples for the attachment of tubing to respiratory therapy equipment shall conform to the dimensions given in Figure 1 a), and also, if corrugated, shall conform to 1 b).

3.2 Performance

When tested as described in A.2, nipples shall neither fracture nor distort by more than 2 mm.

4 Weight-bearing screw-threaded connectors

4.1 Weight-bearing screw-threaded connectors for oxygen shall comply with Figure B.1.

4.2 Weight-bearing screw-threaded connectors for air shall comply with Figure B.2.

5 Tubing

5.1 General

Material used for tubing shall be :

a) compatible with oxygen or air or any other gas mixture specified by the manufacturer ;

b) non-toxic ;