ILNAS

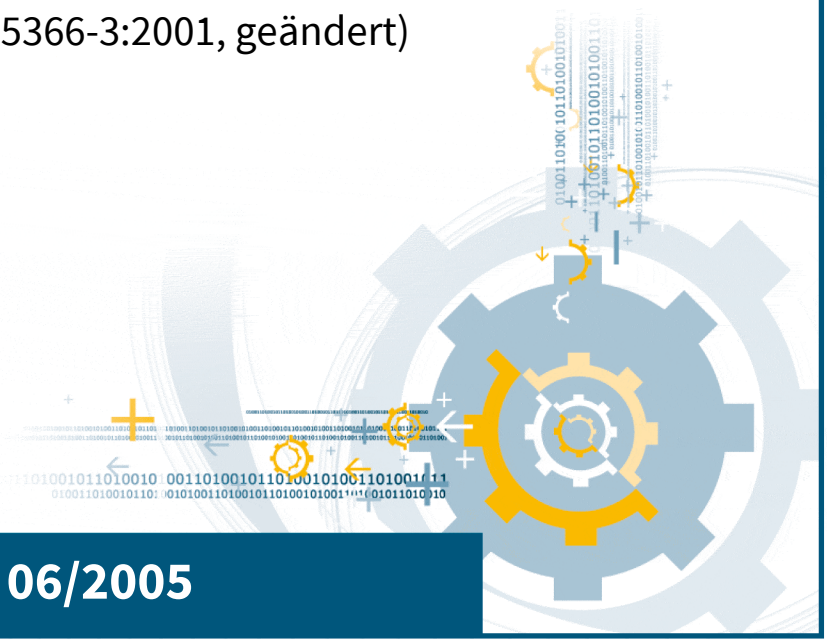
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 1282-2:2005

Tracheostomy tubes - Part 2: Paediatric tubes (ISO 5366-3:2001, modified)

Tubes de trachéostomie - Partie 2: Tubes pédiatriques (ISO 5366-3:2001, modifiée)

Tracheotomietuben - Teil 2: Pädiatrische Tuben (ISO 5366-3:2001, geändert)



06/2005

National Foreword

This European Standard EN 1282-2:2005 was adopted as Luxembourgish Standard ILNAS-EN 1282-2:2005.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

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English version

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This European Standard was approved by CEN on 25 April 2005.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

The text of the International Standard ISO 5366-3:2001, including Corrigendum 1:2003 from Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) has been taken over as a European Standard by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI, with common modifications which are indicated by a straight line in the margin of the text.

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 December 2005 and conflicting national standards shall be withdrawn at the latest by December 2005.

This document supersedes EN 1282-2:1997.

This document 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 document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

ISO 5366 is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and/or rubber.

EN ISO 5366-1 gives requirements for adult tracheostomy tubes made of plastics materials and/or rubber.

This document gives requirements for paediatric tracheostomy tubes with an inside diameter from 2,0 mm to 6,0 mm.

Paediatric tracheostomy tubes are primarily intended for use with infants and children who may require anaesthesia, artificial ventilation, relief of upper airway obstruction or other respiratory therapy.

An infant or child differs from an adult, not only in size but especially with regard to airway anatomy and respiratory physiology; thus airway equipment for paediatric patients differs from that for adults in size and also in basic design. It should be noted that, although this document gives some requirements for cuffs, cuffs are seldom provided on the smaller sizes of paediatric tubes.

This document gives requirements for those characteristics of tracheostomy tubes that can be standardized and which are important for patient safety. It does not require the connector to be permanently attached to the tube, as this may be impractical with infants and small children. Other acceptable methods of connecting these components are available, and this document makes provision for them. This document does not limit the range of tube designs needed to match the variety of paediatric anatomy, lesions and space limitations encountered.

The method of describing tube dimensions and configuration has been devised with the aim of assisting the clinician in the selection of a suitable tube to conform as far as possible to a particular patient's anatomy. Size is designated by inside diameter, which is important because of its relation to resistance to gas flow. Because the stomal and tracheal diameters are important when selecting tubes, it is considered essential that the outside diameter be stated for each size of tube.

A tracheostomy tube can increase resistance to gas flow. For tubes with a given outside diameter, differences in wall thickness have a major influence on the resistance to gas flow, especially in the smaller sizes of paediatric tracheostomy tubes.

Flammability of tracheostomy tubes, for example if flammable anaesthetics, electrosurgical units or lasers are used in oxidant-enriched atmospheres, is a well-recognized hazard[1] addressed by appropriate clinical management, which is outside the scope of this document.

[1] See ISO/TR 11991.

1 Scope

This European Standard specifies requirements for paediatric tracheostomy tubes made of plastics materials and/or rubber having inside diameters from 2,0 mm to 6,0 mm. Requirements for paediatric tracheostomy tube connectors and adaptors are also given.

This document is not applicable to specialized tracheostomy tubes.

2 Normative references

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.

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be labelled "STERILE"*

EN ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets (ISO 5356-1:2004)*

EN ISO 5366-1:2004, *Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)*

EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10933-1:2003)*

EN 20594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 5361, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 11607, *Packaging for terminally sterilized medical devices*

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN ISO 5366-1:2004 and the following apply.

3.1
paediatric tracheostomy tube
tube designed for insertion into the trachea of an infant or child through a tracheostomy

3.2
paediatric tracheostomy tube connector
tubular component which fits directly into the paediatric tracheostomy tube

3.3
machine end
(paediatric tracheostomy tube connector) end of the component nearest the machine which is intended to mate with the breathing system of an anaesthetic machine or lung ventilator

3.4
patient end
(paediatric tracheostomy tube connector) end of the component nearest the patient which is inserted into the paediatric tracheostomy tube