Irish Standard
I.S. EN ISO 5366-1:2009

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

I.S. EN ISO 5366-1:2009

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

Matériel d'anesthésie et de réanimation respiratoire - Tubes de trachéostomie - Partie 1: Tubes et raccords pour adultes (ISO 5366-1:2000)

Anästhesie- und Beatmungsgeräte - Tracheotomietuben - Teil 1: Tuben und Verbindungsstücke zur Anwendung bei Erwachsenen (ISO 5366-1:2000)

This European Standard was approved by CEN on 21 March 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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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of ISO 5366-1:2000 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 5366-1:2009 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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 supersedes EN ISO 5366-1:2004.

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 EC Directive.

For relationship with EC Directive, 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, 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.

Endorsement notice

The text of ISO 5366-1:2000 has been approved by CEN as a EN ISO 5366-1:2009 without any modification.

Annex ZA
(Informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 – Correspondence between this European Standard and EU Directives

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
1	N/A	
2	N/A	
3	N/A	
4	1, 2 a), 3	
5	1, 2 a), 3, 7.1 a), 7.1 b), 7.2	
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6.1.4	7.5	
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8.3.2 e)	13.3 b)	
8.3.2 f)	13.3 b)	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
8.3.2 g)	13.3 a)	
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8.3.2 i)	8.6, 13.6 h)	
8.3.2 j)	8.1, 8.3, 8.7, 13.2, 13.3 b), c)	
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C.1.2	13.6 h)	
C.1.3	9.3	
-	1 (2nd paragraph, 1st dash) (2nd paragraph, 2nd dash)	These parts of this Essential Requirement are not addressed in this Standard
-	6a)	This part of this Essential Requirement is not addressed in this Standard
-	7.1 (3rd dash)	This part of this Essential Requirement is not addressed in this Standard
-	7.5 (1st paragraph)	This part of this Essential Requirement is not fully addressed in this European Standard
-	7.5 (2nd paragraph)	This part of this Essential Requirement is not fully addressed in this European Standard
-	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
-	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.6 (h)(3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
N/A = not applicable		

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

I.S. EN ISO 5366-1:2009

INTERNATIONAL STANDARD

ISO 5366-1

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2000-12-15

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2001-09-01

Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part 1: Tubes and connectors for use in adults

Matériel d'anesthésie et de réanimation respiratoire — Tubes de trachéostomie —

Partie 1: Tubes et raccords pour adultes

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 5366 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5366-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This fourth edition cancels and replaces the third edition of ISO 5366-1 and the second edition of ISO 5366-2 (ISO 5366-1:1994 and ISO 5366-2:1993), which have been technically revised.

ISO 5366 consists of the following parts, under the general title *Anaesthetic and respiratory equipment — Tracheostomy tubes*:

— *Part 1: Tubes and connectors for use in adults*

— *Part 3: Paediatric tracheostomy tubes*

Annexes A and B form a normative part of this part of ISO 5366. Annex C is for information only.

Introduction

ISO 5366-1 is one of a series of International Standards dealing with anaesthetic equipment, and is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics materials and/or rubber. Specialized tubes, for example those without a connector at the machine end intended for spontaneously breathing patients, and those with reinforced walls or tubes made of metal are excluded from the scope of this part of ISO 5366.

This part of ISO 5366 specifies requirements for tracheostomy tubes with an inside diameter of 6,5 mm or greater. ISO 5366-3 specifies requirements for tracheostomy tubes with an inside diameter from 2,0 to 6,0 mm for paediatric use.

The method of describing tube dimensions and configuration has been devised in order to assist 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.

Cuffed tracheostomy tubes can be characterized by a combination of the tube inside and outside diameters and by the cuff resting diameter.

The relationship of cuff and tracheal diameters dictates the intra-cuff pressures required to provide a seal. Excessive pressure on the tracheal wall can obstruct capillary blood flow.

A range of cuff designs is available to meet the particular clinical requirements. This part of ISO 5366 requires that the resting diameter of the cuff is marked on the unit package, as this information allows the clinician to match the product to the application.

A 15 mm male conical connector in accordance with ISO 5356-1 should be used for tracheostomy tubes, as for tracheal tubes, to ensure compatibility with the breathing system of an anaesthetic machine or ventilator.

The tracheostomy tube connector should be permanently attached to the tracheostomy tube to prevent inadvertent disconnection of the connector from the tube.

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)] that is addressed by appropriate clinical management, and is outside the scope of this part of ISO 5366.

1) See ISO/TR 11991.

Anaesthetic and respiratory equipment — Tracheostomy tubes —

Part 1:
Tubes and connectors for use in adults

1 Scope

This part of ISO 5366 specifies requirements for tracheostomy tubes made of plastics materials and/or rubber having inside diameters of 6,5 mm or greater. Such tubes are primarily designed for patients who require anaesthesia, artificial ventilation or other respiratory support, but need not be restricted to these uses.

This part of ISO 5366 is not applicable to specialized tubes, and does not address flammability of tracheostomy tubes.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 5366. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 5366 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*.

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*.

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*.

ISO 11607, *Packaging for terminally sterilized medical devices*.

EN 556 :1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "STERILE"*.

3 Terms and definitions

For the purposes of this part of ISO 5366, the terms and definitions given in ISO 4135 and the following apply.

3.1
tracheostomy tube
tube designed for insertion into the trachea through a tracheostomy

NOTE See Figure 1 a) and b) for an illustration of a typical tracheostomy tube and the associated nomenclature.