ICS 11.040.10 SLOVENSKÁ TECHNICKÁ NORMA Marec 2017

STN	**Anestetické a respiračné prístroje. Orofaryngeálne dýchacie cesty (ISO 5364: 2016).**	**STN EN ISO 5364** 85 2140

Anaesthetic and respiratory equipment - Oropharyngeal airways (ISO 5364:2016)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/17

Obsahuje: EN ISO 5364:2016, ISO 5364:2016

Oznámením tejto normy sa od 30.09.2019 ruší
STN EN ISO 5364 (85 2140) zo septembra 2011

124232

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 5364

September 2016

ICS 11.040.10

Supersedes EN ISO 5364:2011

English Version

Anaesthetic and respiratory equipment - Oropharyngeal airways (ISO 5364:2016)

Matériel d'anesthésie et de réanimation respiratoire - Canules oropharyngées (ISO 5364:2016)

Anästhesie- und Beatmungsgeräte - Oropharyngealtuben (ISO 5364:2016)

This European Standard was approved by CEN on 15 July 2016.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

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

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 5364:2016 E

Contents

Page

European foreword

This document (EN ISO 5364:2016) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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 2017, and conflicting national standards shall be withdrawn at the latest by September 2019.

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 5364:2011.

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.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard “within the meaning of Annex ZA", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table – Correlations between normative references and dated EN and ISO/IEC standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO 4135	EN ISO 4135:2001	ISO 4135:2001
ISO 7000	—	ISO 7000:2014
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 11607-1	EN ISO 11607-1:2009 + A1:2014	ISO 11607-1:2006 + AMD 1:2014
ISO 15223-1	EN 15223-1:—[1]	ISO 15223-1:2015[1]

EN 556-1:2001	EN 556-1:2001	—
1 The graphical symbols in ISO 7000 are also available on line in the ISO web store. For more information, consult http://www.iso.org/iso/publications_and_e-products/databases.htm?=.		

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 5364:2016 has been approved by CEN as EN ISO 5364:2016 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 Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] / [M/295 concerning the development of European Standards related to medical devices] / [reference number and title of any other standardization request as relevant] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 160].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.1 (second indent)	5 10.3.1 c) 10.4 C)	Partly covered. There are no requirements for materials apart from a requirement to indicate the presence of natural rubber (latex), if applicable.
8.1	8 9.1 9.2 9.2	Covered on for packaging of sterile devices.
8.3	9.3	Partly addressed by 9.3 which mandates the requirements of ISO 11607-1 that the

		packaging is suitable to prevent contamination during transportation and use.
8.7	9.1	Partly covered. Marked sterile if appropriate
9.2 (first two indents)	4 6 7	Partly covered to address only the risk of injury in connection with their physical features by specifying sizing and marking conventions for the length and ID of the airway and by testing for collapse and patency.
12.7.1	6	Partly covered with a requirement to limit sharp edges.
13.1	9 10 11	
13.2	10.3.3 10.3.4	Covered only for the use of identification colours.
13.3 b)	10.3.1 a) 10.3.3 10.5 a) 10.5 b)	
13.3 c)	10.4 a) 10.5 e)	
13.3 d)	10.5 d)	To cover this ER fully, the batch number must be preceded by the word 'LOT'.
13.3 e)	10.5 f)	To cover this ER fully, the 'strong' recommendation to state the use by date is mandatory.
13.3 f)	10.4 b) 10.5 f)	Only the first sentence is covered.
13.3 k)	10.3.1 c) 10.4 b) 10.4 c) 10.5 f)	Limited to indications only of single use and the presence of natural rubber (latex).
13.3 m)	10.5 e)	To cover th is ER fully, the recommendation to provide the method of sterilisation is mandatory (if applicable).
13.6 h) (firs paragraph only)	11.1	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

STN EN ISO 5364: 2017

INTERNATIONAL STANDARD

ISO 5364

Fifth edition
2016-09-01

Anaesthetic and respiratory equipment — Oropharyngeal airways

Matériel d'anesthésie et de réanimation respiratoire — Canules oropharyngées

Reference number
ISO 5364:2016(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This fifth edition cancels and replaces the fourth edition (ISO 5364:2008), which has been technically revised.

Throughout this International Standard, text for which rationale is provided in Annex A is indicated by an asterisk (*).

Major changes in this edition include new legibility test methods and requirements and a colour code to indicate designated size.

Introduction

This International Standard specifies dimensions and other requirements for oropharyngeal airways.

Airway size is designated by length, which is important when selecting an oropharyngeal airway to hold forward the base of the tongue to prevent obstruction of the airway by the soft tissues.

Airway size is indicated by a legible marking and by a colour code, which are important to allow rapid identification and selection in emergencies.

INTERNATIONAL STANDARD ISO 5364:2016(E)

Anaesthetic and respiratory equipment — Oropharyngeal airways

1 Scope

This International Standard specifies requirements for oropharyngeal airways of plastics materials and/or rubber, including those with a reinforcement insert made of plastics materials and/or metal.

This International Standard is not applicable to metal oropharyngeal airways, nor to requirements concerning flammability of oropharyngeal airways.

Flammability of oropharyngeal airways, for example, if flammable anaesthetics, electrosurgical units, or lasers are used, is a well-recognized hazard. It is addressed by appropriate clinical management, which is outside the scope of this International Standard.

This International Standard is not applicable to supralaryngeal airways without an internal, integral sealing mechanism.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*