ICS 11.040.10, 11.040.25 SLOVENSKÁ TECHNICKÁ NORMA Apríl 2015

STN	**Odsávacie katétre používané v respiračnom trakte (ISO 8836: 2014).**	**STN EN ISO 8836** 85 5833

Suction catheters for use in the respiratory tract (ISO 8836:2014)

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. 03/15

Obsahuje: EN ISO 8836:2014, ISO 8836:2014

Oznámením tejto normy sa ruší
STN EN ISO 8836 (85 5833) zo septembra 2009

120538

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8836

October 2014

ICS 11.040.25; 11.040.10

Supersedes EN ISO 8836:2009

English Version

Suction catheters for use in the respiratory tract (ISO 8836:2014)

Sondes d'aspiration pour les voies respiratoires (ISO 8836:2014)

Absaugkatheter zur Verwendung im Atemtrakt (ISO 8836:2014)

This European Standard was approved by CEN on 25 July 2014.

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 8836:2014 E

Contents

Page

Foreword **3**

Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC** **4**

Foreword

This document (EN ISO 8836:2014) 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 April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

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 8836:2009.

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, 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 8836:2014 has been approved by CEN as EN ISO 8836:2014 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 one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, 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 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this standard.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/subclause (s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC amended by 2007/47/EC	Qualifying remarks/notes
4, 6	7.1 (second, and third indents)	In the EU, competent authorities always require applicable ERs
6.1, 9.1, 9.2	7.2	6.1 mandates that these devices shall satisfy the biological safety testing indicated in ISO 10993-1. 9.1 and 9.2 covers the integrity of the packaging only for devices supplied sterile
4.1.1, 4.1.2, 6	7.3 first sentence	4.1.1, 4.1.2, and 6 mandates a risk assessment be carried out which does not exclude risks associated with materials and the substances with which they may come into contact.
6.8, 10.3.2 i)	7.5	Partly addressed by 6.8 and 10.3.2 i) calls specifically for a warning if phthalates are incorporated
9.1, 9.2, 10.3.2 f) 10.4.2 g)	8.1	9.1 and 10.3.2 f) and 10.4.2 g) mandate that sterile devices are clearly marked according to EN 556–1 mandates the requirements of ISO 11607-1 to ensure that the packaging is suitable to prevent contamination during transportation and use.
9.2	8.3	Partly addressed by 9.2 which mandates the requirements of ISO 11607-1 that the packaging is suitable to prevent contamination during transportation and use.
9.1	8.4	9.1 mandates that sterile devices satisfy 4.1 of EN 556–1

9.1	8.5	9.1 mandates that sterile devices satisfy 4.1 of EN 556–1
10.3.2 f) 10.4.2 g)	8.7	Partly covered. Marked sterile if appropriate
7.3 7.4.1 7.4.2 7.4.6 8.1 8.4 8.5	9.1	Generally covered by mandating construction and testing of interface connectors, and leakage and resistance when attached to breathing systems.
5.1 5.2 7.1 7.2 7.4.1 7.4.3 7.4.4 7.4.5 8.1 8.2 8.3 8.6	9.2 (first three requirements)	Partly covered to address only the risk of injury in connection with their physical features by specifying sizing and marking conventions for the ID/OD and length of the catheter, design and construction of the tip, additional protections if provided by components of a closed suction catheter, security of construction, performance of the catheter shaft and vacuum control device, and radiopacity.
10.1.3 10.1.4 10.1.5 10.1.6	10.1 (first sentence)	Partly covered to address indication of tip angle, length measurement and marking in cm and colour codes for length marks, if provided. Limits of accuracy are specified in the standard and not disclosed by the manufacturer.
10.1.3 10.1.4 10.1.5 10.1.6	10.2	Tip direction and length mark positions are mandated to provide ergonomic visibility during intubation.
10.1.4 10.1.5	10.3	Length marking is mandated using SI units (mm). Additional use of (cm) is permitted.
7.4.2.1 7.4.2.2 7.4.5	12.7.4	Suction catheter gas connectors are mandated to comply with ISO 5356-1 for 15 mm and 22 mm connectors. Suction catheter flushing system connectors are mandated to comply with ISO 594-1 or ISO 594-2 for Luers.

10 Annex A, Clause 4	13.1	Covered by mandating marking and labelling and instructions on the suction catheter, connector, unit label, shelf/multi-unit label and instructions for use. Annex A, Clause 4 draws attention to consideration of disclosure of specific labelling and instructions for intended use that may deviate from the currently accepted medical practice.
10.2	13.2	Symbols are mandated in 10.2 to conform to EN 1041, ISO 7000 or ISO 15223-1 and ISO 15223-2
10.3.2 c) 10.4.2 c)	13.3 a)	Manufacturer identification mandated on the device and on individual pack or any insert. Authorized representative mandated on the individual pack or any insert.
10.3.2 10.4.2	13.3 b)	
10.3.2 f) 10.4.2 g)	13.3 c)	
10.4.2 d)	13.3 d)	Batch code preceded by the word “LOT” mandated for EU countries.
10.4.2 e)	13.3 e)	'Use by date' is partly addressed 'where appropriate' as 'an indication of the date by which the catheter should be used'. The EU regulation makes it mandatory.
10.4.2 g) 10.4.2 i)	13.3 f)	
Annex A, Clause 4	13.3 j)	Annex A, Clause 4 draws attention to consideration of disclosure of specific labelling and instructions for intended use that may deviate from the currently accepted medical practice.
10.3.2 f) 10.4.2 g)	13.3 m)	
10.3 10.4 f)	13.6, a), b), c)	Instructions are limited to the mandated information on labelling of individual packs, and preparation for use instructions on the shelf/multi-pack label only.
10.4.2 h)	13.6 h)	Limited to mandated instructions for cleaning, disinfection, and resterilization on the shelf/multi-pack label only. Risks associated with the reuse of devices marked for single use are covered partly by the risk management file and use of the informative Annex F Hazard identification for risk assessment
10.4.2 f)	13.6 i)	Limited to mandated instructions for preparation for use on the shelf/multi-pack label only.

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

INTERNATIONAL STANDARD

ISO 8836

Fourth edition
2014-10-15

Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

Reference number
ISO 8836:2014(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword ... **v**

Introduction ... **vi**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **2**

4 *General requirements for open and closed suction catheters ... **5**
4.1 Risk management ... 5
4.2 Safety ... 6

5 Specific requirements for open and closed suction catheters ... **6**
5.1 Size and length designations ... 6
5.2 *Dimensions ... 6

6 Materials ... **7**

7 *Design ... **8**
7.1 Lumen of the suction catheter ... 8
7.2 Suction catheter tip ... 8
7.3 *Suction catheter connector ... 8
7.4 Additional requirements for closed suction catheters ... 10

8 Performance requirements ... **12**
8.1 Security of construction ... 12
8.2 Shaft performance ... 12
8.3 *Vacuum control device performance ... 13
8.4 *Leakage ... 13
8.5 *Resistance to flow ... 13
8.6 *Radiopacity ... 13

9 Requirements for suction catheters supplied sterile ... **13**
9.1 Sterility assurance ... 13
9.2 Packaging of suction catheters supplied sterile ... 14

10 Marking ... **14**
10.1 Marking on suction catheters ... 14
10.2 Use of symbols ... 15
10.3 Labelling of individual packs ... 16
10.4 Labelling of shelf/multi-unit packs ... 16

Annex A (informative) **Rationale** ... **18**

Annex B (normative) **Test method for security of attachment** ... **21**

Annex C (normative) **Measurement of residual vacuum** ... **22**

Annex D (normative) **Method of testing leakage** ... **24**

Annex E (informative) **Hazard identification for risk assessment** ... **25**

Bibliography ... **27**

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. 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. 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 fourth edition of ISO 8836 cancels and replaces the third edition (ISO 8836:2007), of which it constitutes a technical revision.

Introduction

This International Standard specifies dimensions and requirements for **suction catheters** for use in the respiratory tract. It is concerned with the basic requirements and method of size designation of both **open** and **closed suction catheters** made of flexible materials.

The method of describing tube dimensions and configuration has been devised in order to assist clinicians in the selection of the most suitable **suction catheter** for a particular patient. Size is designated by outside diameter which is important when selecting a catheter because of its relationship to the ease with which the catheter can be passed through a **tracheal** or **tracheostomy tube**.[2][3][4]

Revisions in this fourth edition are intended to harmonize this International Standard with recent amendments in the European Medical Device Directive.

Major technical revisions in this edition include requirements for **closed suction catheters**, new requirements to harmonize this International Standard with requirements for critical care **ventilators**, and **risk management**.

Terms defined in Clause 3 of this International Standard or in ISO 4135[1] appear in **bold** type.

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

INTERNATIONAL STANDARD **ISO 8836:2014(E)**

Suction catheters for use in the respiratory tract

1 Scope

This International Standard specifies requirements for **suction catheters**, including **closed suction catheters**, made of flexible materials and intended for use in suctioning of the respiratory tract.

Angled-**tip suction catheters** (e.g. Coudé catheters) and **suction catheters** with aspirator collectors are not considered to be specialized and are therefore included in the scope of this International Standard.

Suction catheters intended for use with flammable anaesthetic gases or agents, lasers or electrosurgical equipment are not covered by this International Standard.

NOTE See ISO/TR 11991 for guidance on airway management during laser surgery of the upper airway.[6]

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable to 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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

*ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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

ISO 5367:—[1)], *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*[2)]

ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment*

ISO 10079-2, *Medical suction equipment — Part 2: Manually powered suction equipment*

ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source*

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

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

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

1) To be published. (Revision of ISO 5367:2000)

2) 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?=.

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

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

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

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 of medical devices*

EN 15986, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

ASTM D3002:2007, *Standard Guide for Evaluation of Coatings Applied to Plastics*

ASTM F640, *Standard Test Methods for Determining Radiopacity for Medical Use*