HINGAMISTEEDES KASUTATAVAD ASPIRATSIOONIKATEETRID

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 8836:2014 sisaldab Euroopa standardi EN ISO 8836:2014 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8836:2014 consists of the English text of the European standard EN ISO 8836:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.10.2014.	Date of Availability of the European standard is 29.10.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.10, 11.040.25

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8836

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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.

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

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

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