SLOVENSKI STANDARD
SIST EN ISO 8835-3:2009/A1:2011

01-januar-2011

Inhalacijski anestezijski sistemi - 3. del: Sistemi za prenos in sprejem sistemov za odstranjevanje anestezijskih plinov (ISO 8835-3:2007/AMD 1:2010)

Inhalational anaesthesia systems - Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007/AMD 1:2010)

Systeme für die Inhalationsanästhesie - Teil 3: Weiterleitungs- und Aufnahmesysteme von aktiven Anästhesiegas-Fortleitungssystemen (ISO 8835-3:2007/AMD 1:2010)

Systèmes d'anesthésie par inhalation - Partie 3: Systèmes de transfert et de réception des systèmes d'évacuation des gaz d'anesthésie (ISO 8835-3:2007/AMD 1:2010)

Ta slovenski standard je istoveten z: **EN ISO 8835-3:2009/A1:2010**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 8835-3:2009/A1:2011 **en**

EUROPEAN STANDARD

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EN ISO 8835-3:2009/A1

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English Version

Inhalational anaesthesia systems - Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007/AMD 1:2010)

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This amendment A1 modifies the European Standard EN ISO 8835-3:2009; it was approved by CEN on 14 October 2010.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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Ref. No. EN ISO 8835-3:2009/A1:2010: E

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Foreword

This document (EN ISO 8835-3:2009/A1:2010) has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 8835:2009 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2011, and conflicting national standards shall be withdrawn at the latest by April 2011.

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 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.

For relationship with EU 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, Croatia, 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 8835-3:2007/AMD 1:2010 has been approved by CEN as a EN ISO 8835-3:2009/A1:2010 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 Union 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 - Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	2, 12.7.4	
4.1	7.5 (1st paragraph)	This relevant Essential Requirement is not completely addressed in this EN.
11, 12	1, 2nd paragraph, 1st and 2nd dash	These relevant Essential Requirements are not fully addressed in this EN
11, 12	13.1	
11, 12	13.3 b)	
11 d)	13.6 h)	
	13.6 q)	This relevant Essential Requirement is not addressed in this EN
12 b)	13.3 a)	This relevant Essential Requirement is not completely addressed in this EN

Warning – Other requirements and other EU Directives may be applicable to the products falling within the scope of this International standard.

INTERNATIONAL STANDARD

ISO 8835-3

Second edition
2007-08-15

AMENDMENT 1
2010-10-15

Inhalational anaesthesia systems —

Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems

AMENDMENT 1

Systèmes d'anesthésie par inhalation —

Partie 3: Systèmes de transfert et de réception des systèmes d'évacuation des gaz d'anesthésie

AMENDEMENT 1

Reference number
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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 8835-3:2007 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.