SLOVENSKI STANDARD
SIST EN ISO 8835-2:2009

01-julij-2009

Nadomeġļa:
SIST EN ISO 8835-2:2008

Inhalacijski anestezijski sistemi - 2. del: Anestezijski dihalni sistemi (ISO 8835-2:2007)

Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)

Systeme für die Inhalationsanästhesie - Teil 2: Anästhesie-Atemsysteme (ISO 8835-2:2007)

Systèmes d'anesthésie par inhalation - Partie 2: Systèmes respiratoires d'anesthésie (ISO 8835-2:2007)

Ta slovenski standard je istoveten z: **EN ISO 8835-2:2009**

ICS:

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

SIST EN ISO 8835-2:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8835-2

April 2009

ICS 11.040.10

Supersedes EN ISO 8835-2:2007

English Version

Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)

Systèmes d'anesthésie par inhalation - Partie 2: Systèmes respiratoires d'anesthésie (ISO 8835-2:2007)

Systeme für die Inhalationsanästhesie - Teil 2: Anästhesie-Atemsysteme (ISO 8835-2:2007)

This European Standard was approved by CEN on 14 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.

CEN members are the national standards bodies of 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 United Kingdom.

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

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Ref. No. EN ISO 8835-2:2009: E

Contents

Page

Foreword

The text of ISO 8835-2:2007 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 8835-2:2009 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 8835-2:2007.

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.

Other European Standards relating to anaesthetic workstations and their components prepared by CEN/TC 215 which together with EN 60601-2-13:2006, replace appropriate portions of EN 740:1998, are:

– EN ISO 8835-2:2007, Inhalational anaesthesia systems – Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)

– EN ISO 8835-3:2007, Inhalational anaesthesia systems – Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007)

– EN ISO 8835-4:2004, Inhalational anaesthesia systems – Part 4: Anaesthetic vapour delivery devices (ISO 8835-4:2004)

– EN ISO 8835-5:2004, Inhalational anaesthesia systems – Part 5: Anaesthetic ventilators (ISO 8835-5:2004)

Attention is also drawn to ISO/TS 18835:2004, Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment.

Annex RR of EN 740:1998 (Method of test for draw-over vaporizers used with emergency anaesthetic equipment) is not superseded.

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 8835-2:2007 has been approved by CEN as a EN ISO 8835-2:2009 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 Directive 93/42/EEC

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1 to 6	
4.1	1 to 6 and 7 (except 7.4 and 7.5, 2nd and 3rd paragraphs)	The relevant Essential Requirement 7.5, 1st paragraph, is not fully addressed in this EN. The relevant Essential Requirements 7.5 (2nd and 3rd paragraphs) are not addressed in this EN.
-	6a)	This relevant Essential Requirement is not addressed in this EN.
4.2	9.2	
4.3	12.6	
5	9, 12.7, 12.9	
5.2	9, 12.7	
6	9, 12.7	
7	9.2, 12.7, 12.8	
8.1	9, 12.9	
8.2 to 8.4	9, 12.8	
9.1	9, 12.7	
9.2, 9.3	9, 12.7, 12.8	
9.4	9	
10	9, 10	
11	9	

Table ZA.1 (continued)

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
12	9 and 13 (except 13.6 h and 13.6q)	The relevant Essential Requirements 13.3 a) and 13.3 f) are not fully addressed in this EN.
13	9 and 13	The relevant Essential Requirements 13.3 a) and 13.3 f) are not fully addressed in this EN. The relevant Essential Requirements 13.6 h), 2nd paragraph, last two sentences and 13.6 q) are not addressed in this EN

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

INTERNATIONAL STANDARD

ISO 8835-2

Third edition
2007-08-15

Inhalational anaesthesia systems —

Part 2: Anaesthetic breathing systems

Systèmes d'anesthésie par inhalation —

Partie 2: Systèmes respiratoires d'anesthésie

Reference number
ISO 8835-2:2007(E)

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Contents

Page