SLOVENSKI STANDARD
SIST EN ISO 8835-5:2004

01-november-2004

Nadomeġļa:
SIST EN 740:2000
SIST EN 740:2000/AC:2000

Inhalacijski anestezijski sistemi – 5. del: Anestezijski ventilatorji (ISO 8835-5:2004)

Inhalational anaesthesia systems - Part 5: Anaesthesia ventilators (ISO 8835-5:2004)

Systeme für die Inhalationsanästhesie - Teil 5: Anästhesie-Beatmungsgeräte (ISO 8835-5:2004)

Systemes d'anesthésie par inhalation - Partie 5: Ventilateurs d'anesthésie (ISO 8835-5:2004)

Ta slovenski standard je istoveten z: **EN ISO 8835-5:2004**

ICS:

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

SIST EN ISO 8835-5:2004 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8835-5

May 2004

ICS 11.040.10

Supersedes EN 740:1998

English version

Inhalational anaesthesia systems - Part 5: Anaesthesia ventilators (ISO 8835-5:2004)

Systèmes d'anesthésie par inhalation - Partie 5: Ventilateurs d'anesthésie (ISO 8835-5:2004)

Systeme für die Inhalationsanästhesie - Teil 5: Anästhesie-Beatmungsgeräte (ISO 8835-5:2004)

This European Standard was approved by CEN on 6 May 2004.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 8835-5:2004: E

Foreword

This document (EN ISO 8835-5:2004) 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 November 2004, and conflicting national standards shall be withdrawn at the latest by November 2009.

This document supersedes EN 740:1998.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 8835-5:2004 has been approved by CEN as EN ISO 8835-5:2004 without any modifications.

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.

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 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.

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

INTERNATIONAL STANDARD

ISO 8835-5

First edition
2004-05-15

Inhalational anaesthesia systems —

Part 5: Anaesthetic ventilators

Systèmes d'anesthésie par inhalation —

Partie 5: Ventilateurs d'anesthésie

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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.

ISO 8835-5 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

ISO 8835 consists of the following parts, under the general title *Inhalational anaesthesia systems*:

— *Part 2: Anaesthetic breathing systems for adults*

— *Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*

— *Part 4: Anaesthetic vapour delivery devices*

— *Part 5: Anaesthetic ventilators*

NOTE ISO 8835-1, *Medical electrical equipment — Part 1: Particular requirements for the safety of anaesthetic workstations,* was withdrawn in 1998 and replaced by the second edition of IEC 60601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems.*