SLOVENSKI STANDARD

SIST EN ISO 23747:2008

01-april-2008

Nadomeģ a:

SIST EN 13826:2003

Anestezijska in dihalna oprema - Merilniki najveļ jega pretoka zraka med izdihom za oceno funkcije pljuļ pri spontano dihajoļ ih ljudeh (ISO 23747:2007)

Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2007)

Anästhesie- und Beatmungsgeräte - Spirometer für den exspiratoischen Spitzenfluss zur Bewertung der Lungenfunktion bei spontan atmenden Menschen (ISO 23747:2007)

Matériel d'anesthésie et de réanimation respiratoire - Débitmetres de débit expiratoire de pointe pour l'évaluation de la fonction pulmonaire chez les etres humains respirant spontanément (ISO 23747:2007)

Ta slovenski standard je istoveten z: **EN ISO 23747:2007**

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11.040.10

SIST EN ISO 23747:2008 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23747

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Supersedes EN 13826:2003

English Version

Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2007)

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This European Standard was approved by CEN on 28 June 2007.

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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.

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

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

Foreword

This document (EN ISO 23747:2007) 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of an identical text or by endorsement, at the latest by January 2008, and conflicting national standards shall be withdrawn at the latest by January 2008.

This document supersedes EN 13826:2003.

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, 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.

Endorsement notice

The text of ISO 23747:2007 has been approved by CEN as EN ISO 23747:2007 without any modifications.

Annex ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC

This International 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 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.

Table ZA.1 — Correspondence between this International Standard and EU Directives

Clause(s)/Subclause(s) of this International Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments[a]
All	1, 2, 3	And via IEC 60601-1
4.1	12.6	And via IEC 60601-1, Clauses 4, 8
4.2	9.2	And via IEC 60601-1, Clauses 4, 5, 9, and Subclauses 8.9.1.5, 12.2, 15.2
5	5, 13.1	And via IEC 60601-1, Clauses 4, 7 and Subclauses 7.2.17, 7.9.3.1, 15.3.7,16.2
5.1 a)	10.3	And via IEC 60601-1, Subclause 7.4.3
5.1 b)	10.1, 10.2, 12.9	And via IEC 60601-1, Clause 4 and Subclauses 7.4, 7.5, 7.6, 7.8, 12.1, 12.2
5.1 c)	12.9	And via IEC 60601-1, Clause 4, and Subclauses 7.4, 7.5, 7.6, 7.8, 12.2
5.1 d)	12.9	And via IEC 60601-1, Clause 4, and Subclauses 7.4, 7.5, 7.6, 7.8, 12.2
5.1 e)	12.9	And via IEC 60601-1, Clause 4, and Subclauses 7.4, 7.5, 7.6, 7.8, 12.2
5.2.1 a)	9.1, 12.9	And via IEC 60601-1, Clauses 4, 14, 16, and Subclauses 7.4, 7.5, 7.6, 7.8, 8.2, 8.3, 8.5.2, 8.5.5, 8.6.6, 8.10.3, 8.10.4, 9,11.2.2, 11.4, 11.5, 12.2
5.2.1 b)	13.3 a)	And via IEC 60601-1, Subclause 7.2.2
5.2.1 c)	13.2, 13.3 d)	And via IEC 60601-1, Subclauses 7.2, 7.4, 7.5, 7.6
5.2.1 d)	13.6 n)	
5.2.2 a)	13.3 b)	And via IEC 60601-1, Subclause 7.2.2
5.2.2 b)	8.3, 8.7, 13.2, 13.3 c)	And via IEC 60601-1, Subclauses 7.2, 7.4, 7.5, 7.6, 11.6.7

Clause(s)/Subclause(s) of this International Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments[a]
5.2.2 c)	13.3 e)	
5.2.2 d)	13.2, 13.3 f)	And via IEC 60601-1, Subclauses 7.2.1, 7.4, 7.5, 7.6
5.2.2 e)	13.3 i)	And via IEC 60601-1, Subclause 7.2.17
5.2.2 f)	13.4	And via IEC 60601-1, Subclauses 7.9.2.1, 16.2
5.3	13.6 a)	And via IEC 60601-1, Subclauses 7.9.1, 7.9.2, 16.2
5.3 b)	13.1, 13.3 i), 13.3 j), 13.3 k)	And via IEC 60601-1, Clause 7 and Subclause 16.2
5.3 c)	13.6 d)	And via IEC 60601-1, Subclauses 7.9.2.6, 7.9.2.8, 7.9.2.9, 7.9.2.13, 7.9.2.16, 9.8.1, 16.2
5.3 d)	13.6 b), 13.6 k)	And via IEC 60601-1, Subclauses 7.9.2.1, 7.9.2.2 ,7.9.2.9,16.2
5.3 e)	13.6 i)	
5.3 f)	7.6, 8.1, 13.6 h)	And via IEC 60601-1, Subclauses 7.9.2.6, 7.9.2.8, 7.9.2.9, 7.9.2.12, 7.9.2.14, 11.3, 11.6.1, 11.6.7, 11.6.8, 13.1.2, 13.2.6, 16.2
5.4 a)	9.1, 13.6 b)	And via IEC 60601-1, Clauses 4, 14, 16, and Subclauses 7.9.2.1, 7.9.2.2 ,7.9.2.9, 8.2, 8.3, 8.5.2, 8.5.5, 8.6.6, 8.10.3, 8.10.4, 9,11.2.2, 11.4, 11.5, 16.2
5.4 b)	10.1, 13.6 p)	And via IEC 60601-1, Clause 4 and Subclause 12.1
5.4 c)	10.1, 13.6 l)	And via IEC 60601-1, Clause 4 and Subclause 12.1
5.4 d)	10.1, 13.6 l)	And via IEC 60601-1, Clause 4 and Subclause 12.1
6	10.1, 10.2	And via IEC 60601-1, Clause 4 and Subclauses 12.1, 12.2
7	3, 10.1	And via IEC 60601-1, Clause 4 and Subclauses 11.1, 12.1
8	4, 9.2, 10.1	And via IEC 60601-1, Clauses 4, 5, 9, 15 and Subclauses 7.9, 8.9.1.5, 12.1, 12.2, 15.2
9	4, 9.2, 10.1	And via IEC 60601-1, Clauses 4, 5, 9, 15 and Subclauses 7.9, 8.9.1.5, 12.1, 12.2, 15.2

Clause(s)/Subclause(s) of this International Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments[a]
10	4, 9.2	And via IEC 60601-1, Clauses 4, 5, 9, 15 and Subclauses 7.9, 8.9.1.5, 12.2, 15.2
11.1	4, 7.3, 8.1, 8.5	And via IEC 60601-1, Clauses 4, 15 and Subclauses 7.9, 11.2, 11.4, 11.5, 11.6, 11.7, 16.2
11.2	8.4	And via IEC 60601-1, Subclause 11.6.7
12	4, 7.1, 7.3, 7.5	And via IEC 60601-1, Clauses 4, 9, 15, and Subclauses 7.9, 11.2, 11.3, 11.4, 11.5, 11.6, 11.7, 13.1.2, 13.2.6, 15.2
13	7.1	And via IEC 60601-1, Clause 9,and Subclauses 11.2, 11.3, 11.4, 11.5, 11.6.8, 11.7, 15.2
—	7.2	Via IEC 60601-1, Subclauses 11.6.6, 11.6.7, 11.7, 15.3.7, 16.2
—	9.3	Via IEC 60601-1, Clause 4, and Subclauses 8.11.6, 11.2, 11.3, 11.4, 11.5, 13.1.2, 15.4.3.5
—	11.3.1	Via IEC 60601-1, Clauses 4, 10, and Subclause 12.4.5.1
—	12.5	Via IEC 60601-1, Clauses 4, 17
—	12.7.1	Via IEC 60601-1, Clauses 4, 9, and Subclause 15.3
—	12.7.2	Via IEC 60601-1, Clause 4 and Subclause 9.6
—	12.7.3	Via IEC 60601-1, Clause 4 and Subclause 9.6
—	12.7.4	Via IEC 60601-1, Clause 4, and Subclauses 8.10.3, 8.10.4, 8.11
—	12.7.5	Via IEC 60601-1, Clause 4, and Subclauses 8.11.4, 11.1, 15.4.1, 16.9.1, 16.9.2.1
—	12.8.2	Via IEC 60601-1, Clause 4, and Subclauses 7.8, 12.3, 12.4
—	13.3 m)	Via IEC 60601-1, Subclauses 6.4, 7.2.17
—	13.5	Via IEC 60601-1, Subclauses 7.2.2, 7.2.4
—	13.6 c)	Via IEC 60601-1, Subclauses 7.9.2.6, 7.9.2.8, 7.9.2.9, 7.9.2.14, 16.2
—	13.6 f)	Via IEC 60601-1, Subclause 7.9.2.2

a The following comments relating to clauses and subclauses of IEC 60601-1:2005 describe the consequences of the general normative reference to IEC 60601-1:2005 made in the requirement 4.1 of the present standard.

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

INTERNATIONAL STANDARD

ISO 23747

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Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

Matériel d'anesthésie et de réanimation respiratoire — Débitmètres à débit de pointe expiratoire pour l'évaluation de la fonction pulmonaire chez les êtres humains respirant spontanément

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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 23747 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.