SLOVENSKI STANDARD

SIST EN ISO 23747:2009

01-julij-2009

Nadomeġļ a:

SIST EN ISO 23747:2008

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 exspiratorischen Spitzenfluss zur Bewertung der Lungenfunktion bei spontan atmenden Menschen (ISO 23747:2007)

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 (ISO 23747:2007)

Ta slovenski standard je istoveten z: **EN ISO 23747:2009**

ICS:

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

SIST EN ISO 23747:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23747

March 2009

ICS 11.040.10

Supersedes EN ISO 23747:2007

English Version

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

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 (ISO 23747:2007)

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

This European Standard was approved by CEN on 24 February 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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

The text of ISO 23747:2007 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 23747:2009 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 September 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 23747:2007.

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 Directives.

For relationship with EC Directives, 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 the United Kingdom.

Endorsement notice

The text of ISO 23747:2007 has been approved by CEN as a EN ISO 23747:2009 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. 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. - 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	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	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
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	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
5.2.2	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
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
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	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
5.3	13.6 a)	And via IEC 60601-1, Subclauses 7.9.1, 7.9.2, 16.2
5.3	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
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
-	6a)	This relevant Essential Requirement is not addressed in this European Standard
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
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
12, 13	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
—	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 products falling within the scope of this International standard.

INTERNATIONAL STANDARD

ISO 23747

First edition
2007-07-15

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

Reference number
ISO 23747:2007(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland