SLOVENSKI STANDARD
SIST EN ISO 23747:2015

01-oktober-2015

Nadomešča:

SIST EN ISO 23747:2009

Anestezijska in dihalna oprema - Merilniki največjega pretoka zraka med izdihom za oceno funkcije pljuč pri spontano dihajočih ljudeh (ISO 23747:2015)

Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2015)

Anästhesie- und Beatmungsgeräte - Spirometer für den exspiratorischen Spitzenfluss zur Bewertung der Lungenfunktion bei spontan atmenden Menschen (ISO 23747:2015)

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 23747:2015)

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

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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 23747:2015)

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This European Standard was approved by CEN on 13 June 2015.

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European foreword

This document (EN ISO 23747:2015) 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of an identical text or by endorsement, at the latest by February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

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 23747:2009.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 23747:2015 has been approved by CEN as EN ISO 23747:2015 without any modification.

Annex ZA
(informative)

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

By agreement between ISO and CEN, this CEN annex is included in the DIS and the FDIS but will not appear in the published ISO document.

This Document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this document 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 document given in Table ZA.1, within the limits of the scope of this document, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this Document and Directive 93/42/EEC

Corresponding essential requirement of Directive 93/42/EEC	Clause/subclause of this Document	Qualifying remarks/notes
7.1	12, 13	The part of ER 7.1 relating to biophysical or modelling research is not addressed.
7.2	—	This relevant ER is not covered by this standard.
7.3	11, 12	
7.5	12	The parts of ER 7.5 relating to phthalates are not addressed.
7.6	—	This relevant ER is not covered by this standard.
8.1	5.3 f), 11.1	
8.3	—	This relevant ER is not covered by this standard.
8.4	11.2	
8.5	—	This relevant ER is not covered by this standard.
8.6	—	This relevant ER is not covered by this standard.
8.7	—	This relevant ER is not covered by this standard.
9.1	5.2.1 a), 5.4 a)	
9.2	4.1, 4.2, 8, 9, 10	

Corresponding essential requirement of Directive 93/42/EEC	Clause/subclause of this Document	Qualifying remarks/notes
9.3	—	This relevant ER is not covered by this standard.
10.1	5.1 b), 5.4 b), 5.4 c), 5.4 d), 6, 7, 8, 9	
10.2	5.1 b), 6	
10.3	5.1 a)	
12.6	4.1	
12.7.1	—	This relevant ER is not covered by this standard.
12.7.2	—	This relevant ER is not covered by this standard.
12.7.3	—	This relevant ER is not covered by this standard.
12.7.4	—	This relevant ER is not covered by this standard.
12.7.5	—	This relevant ER is not covered by this standard.
12.9	5.1 b), 5.1 c), 5.1 d), 5.1 e), 5.2.1 a)	
13.1	5	
13.2	5.2.1 c), 5.2.2 b), 5.2.2 c)	
13.3 a)	5.2.1 b)	
13.3 b)	5.2.2 a)	
13.3 c)	5.2.2 b)	
13.3 d)	5.2.1 c)	
13.3 e)	5.2.2 c)	
13.3 f)	5.2.2 d)	
13.3 i)	5.2.2 e)	
13.3 j)	5.2.2 f)	
13.3 k)	—	This relevant ER is not covered by this standard.
13.3 l)	—	This relevant ER is not covered by this standard.
13.3 m)	5.2.2 b)	
13.4	5.2.2 f), 5.3 a)	
13.5	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 a]	5.3 b)	
13.6 a) [13.3 b]	—	This relevant ER is not covered by this standard.

Corresponding essential requirement of Directive 93/42/EEC	Clause/subclause of this Document	Qualifying remarks/notes
13.6 a) [13.3 c]	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 f]	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 i]	5.3 e)	
13.6 a) [13.3 j]	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 k]	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 l]	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 m]	—	This relevant ER is not covered by this standard.
13.6 b)	—	This relevant ER is not covered by this standard.
13.6 c)	—	This relevant ER is not covered by this standard.
13.6 d)	5.3 b), 5.3 c), 5.3 d), 5.3 f), 5.3 h)	
13.6 h)	5.3 f)	The part of ER 13.6 h) relating to single use is not addressed.
13.6 i)	—	This relevant ER is not covered by this standard.
13.6 k)	5.3 d)	
13.6 l)	—	This relevant ER is not covered by this standard.
13.6 n)	5.3 i)	
13.6 p)	5.3 j)	
13.6 q)	5.3 l)	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this International Standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this Document (according to article 3 of amended Directive 93/42/EEC)

EHSR of 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Qualifying remarks/Notes
1.1.4	–	This relevant EHSR is not covered by this standard.
1.2.2	–	This relevant EHSR is not covered by this standard.
1.5.4	–	This relevant EHSR is not covered by this standard.
3.6.2	–	This relevant EHSR is not covered by this standard.

INTERNATIONAL STANDARD

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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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