SLOVENSKI STANDARD
SIST EN ISO 17510-1:2009

01-julij-2009

Nadomeġļa:
SIST EN ISO 17510-1:2008

Zdravljenje dihanja pri prenehanju dihanja v spanju - 1. del: Oprema za zdravljenje prenehanja dihanja v spanju (ISO 17510-1:2007)

Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007)

Schlafapnoe-Atemtherapie - Teil 1: Schlafapnoe-Atemtherapiegeräte (ISO 17510-1:2007)

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Thérapie respiratoire de l'apnée du sommeil - Partie 1: Équipement de thérapie respiratoire de l'apnée du sommeil (ISO 17510-1:2007)

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Ta slovenski standard je istoveten z: **EN ISO 17510-1:2009**

ICS:

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

SIST EN ISO 17510-1:2009 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17510-1

March 2009

ICS 11.040.10

Supersedes EN ISO 17510-1:2007

English Version

Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007)

Thérapie respiratoire de l'apnée du sommeil - Partie 1: Équipement de thérapie respiratoire de l'apnée du sommeil (ISO 17510-1:2007)

Schlafapnoe-Atemtherapie - Teil 1: Schlafapnoe-Atemtherapiegeräte (ISO 17510-1:2007)

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.

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SIST EN ISO 17510-1:2009

Foreword

The text of ISO 17510-1:2007 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 17510-1:2009 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 17510-1:2007.

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.

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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.

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Endorsement notice

The text of ISO 17510-1:2007 has been approved by CEN as a EN ISO 17510-1:2009 without any modification.

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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 - 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	
4	6, 12.6	
-	6a	This relevant Essential Requirement is not addressed in this European Standard
6	13	
6	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
6.1	2, 13.3 a)	
6.1 aa) to cc)	13.6 c), d)	
6.1 dd)	8.7, 9.1, 13.3, 13.4, 13.5	
6.1 dd) 7th dash	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 e)	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
6.3	10.2, 10.3, 12.9	

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6.8.2	13.6 b), c), h), i), l)	
6.8.3	13.6 c), d), p), n)	
10.1	8.3	
10.101, 10.102	4	
13, 15, 17, 18,19, 20	12.6	
21	5, 9.2, 12.7.1	
23	4, 9.2	
24	4, 12.7.1	
26	12.7.2, 12.7.3	
36	4, 9.2, 11.3.1, 12.5	
38	13.2, 13.4	
39, 40, 41	9.3	
42	9.2, 12.7.5	
43	7.1, 7.2, 9.3	
43.101	7.1, 9.3	
44	4, 7.2, 7.3, 7.5, 7.6, 8.1, 8.6	
44.6	7.6	
44.7	8.3, 8.5	
46	9.2, 10.2, 12.8.2, 12.9	
48	7.2, 7.5	
49	4	
49.101	12.8.1, 12.8.2	
51	12.8.1, 12.8.2	
51.5	2, 12.8.2, 12.9	
51.101	12.8.2	
51.102	10.1, 10.2, 12.8.2	
51.103	10.1, 10.2, 12.8.2	
51.104	4, 12.8.1, 12.8.2	
51.105	4, 12.8.2	
52	12.1	

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54	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
54	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
54.1	12.1, 12.9	
54.101	7.5	
56.3	9.1, 12.7.4	
56.10	12.9	
56.101.1	7.3, 8.1, 8.4	
56.101.2	7.3, 8.1, 8.6	
56.102	9.1	

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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 European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	EHSR o 2006/42/EC	Qualifying remarks/Notes
-	1.1.4	This relevant EHSR is not addressed in this European Standard
6.8.2, 56	1.5.4	This relevant EHSR is not fully addressed in this European Standard
-	1.6.1	This relevant EHSR is not addressed in this European Standard
-	1.6.2	This relevant EHSR is not addressed in this European Standard
-	1.6.3	This relevant EHSR is not addressed in this European Standard
-	3.6.2	This relevant EHSR is not addressed in this European Standard

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Warning – Other requirements and other EU Directives may be applicable to the products falling within the scope of this International standard.

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INTERNATIONAL STANDARD

ISO 17510-1

Second edition
2007-10-01

Sleep apnoea breathing therapy —

Part 1: Sleep apnoea breathing therapy equipment

Thérapie respiratoire de l'apnée du sommeil —

Partie 1: Équipement de thérapie respiratoire de l'apnée du sommeil

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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 17510-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

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This second edition cancels and replaces the first edition (ISO 17510-1:2002) which has been technically revised.

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ISO 17510 consists of the following parts, under the general title *Sleep apnoea breathing therapy*:

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— *Part 1: Sleep apnoea breathing therapy equipment*

— *Part 2: Masks and application accessories*

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