SLOVENSKI STANDARD

SIST EN ISO 17510-1:2008

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Nadomeġļa:

SIST EN ISO 17510-1:2002

SIST EN ISO 17510-1:2002/AC:2004

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)

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

Ta slovenski standard je istoveten z: **EN ISO 17510-1:2007**

ICS:

11.040.10

SIST EN ISO 17510-1:2008 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17510-1

October 2007

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Supersedes EN ISO 17510-1:2002

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 30 September 2007.

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: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 17510-1:2007: E

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Foreword

This document (EN ISO 17510-1:2007) 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 April 2008, and conflicting national standards shall be withdrawn at the latest by April 2008.

This document supersedes EN ISO 17510-1:2002.

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(s).

For relationship with EC 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 the United Kingdom.

Endorsement notice

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

Annex ZA
(informative)

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

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

Clause(s)/sub-clause(s) of this document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
4	6, 12.6	
6	13	
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	
6.3	10.2, 10.3, 12.9	
6.8.2	13.6 b), c), h), i), l)	
6.8.3	13.6 c), d), p), n)	
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13, 15, 17, 18,19, 20	12.6	
21	5, 9.2, 12.7.1	
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44	4, 7.2, 7.3, 7.5, 7.6, 8.1, 8.6	
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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	
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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	

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

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

Reference number
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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*.

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

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

— *Part 1: Sleep apnoea breathing therapy equipment*

— *Part 2: Masks and application accessories*