SLOVENSKI STANDARD

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Nadomeġļa:

SIST EN ISO 17510-2:2003

Zdravljenje dihanja pri prenehanju dihanja v spanju - 2. del: Maske in oprema za nameġļanje (ISO 17510-2:2007)

Sleep apnoea breathing therapy - Part 2: Masks and application accessories (ISO 17510 -2:2007)

Schlafapnoe-Atemtherapie - Teil 2: Masken und Anwendungszubehör (ISO 17510-2:2007)

Thérapie respiratoire de l'apnée du sommeil - Partie 2: Masques et accessoires d'application (ISO 17510-2:2007)

Ta slovenski standard je istoveten z: **EN ISO 17510-2:2007**

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11.040.10

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EUROPEAN STANDARD

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Supersedes EN ISO 17510-2:2003

English Version

Sleep apnoea breathing therapy - Part 2: Masks and application accessories (ISO 17510-2:2007)

Thérapie respiratoire de l'apnée du sommeil - Partie 2: Masques et accessoires d'application (ISO 17510-2:2007)

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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

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Ref. No. EN ISO 17510-2:2007: E

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Foreword

This document (EN ISO 17510-2:2007) 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 17510-2:2003.

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 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 17510-2:2007 has been approved by CEN as a EN ISO 17510-2:2007 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 confers, 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	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
4	13.1, 13.6 a)	
4.1 a)	13.3 a)	
4.1 b)	13.3 b)	
4.1 c)	9.1, 13.6 b) , 13.6 c)	
4.1 d)	9.1, 13.6 b)	
4.1 e)	8.6, 13.6 h)	
4.1 f)	13.3 i)	
4.1 g)	13.3 j)	
4.1 h)	13.3 k)	
4.1 i)	13.3 b), 13.6 i)	
4.1 j)	13.6 k)	
4.1 l)	9.1, 13.6 b)	
4.1 o)	9.1, 13.6 b)	
4.1 m)	13.6 c)	
4.1 n)	13.6 n)	
4.1 q)	13.6 i)	
4.1 r), s)	13.6 d)	
4.2 a)	13.2, 13.3 d), 13.5	

4.2 b)	13.2, 13.3 e), 13.4	
4.2 c)	9.1	
4.2 d)	8.7, 13.2, 13.3 c), 13.3 m)	
4.2 e)	13.6 g)	
5	4, 7.2, 7.5, 7.6	
5.1	12.7.4	
5.2	7.1, 7.3	
5.3	9.2, 12.8.2	
5.4	7.1, 7.3, 8.1, 8.3, 8.4, 8.5	
5.5	9.2, 12.8.1, 12.8.2	
5.6	8.1	
6	12.7.2, 12.7.3	

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

INTERNATIONAL STANDARD

ISO 17510-2

Second edition
2007-10-01

Sleep apnoea breathing therapy —

Part 2: Masks and application accessories

Thérapie respiratoire de l'apnée du sommeil —

Partie 2: Masques et accessoires d'application

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 17510-2 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 17510-2:2003) 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*

Introduction

Sleep apnoea is the clinically significant intermittent absences of normal respiration occurring during sleep. The awareness of the risks associated with sleep apnoea has grown significantly in recent years. As a result, the use of sleep apnoea breathing therapy equipment has become common. This document covers basic safety and essential performance requirements needed to protect patients during use of this equipment.

ISO 17510-2 is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic document for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical electrical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

Throughout this document, text for which a rationale is provided in Annex A is indicated by an asterisk (*).