ILNAS

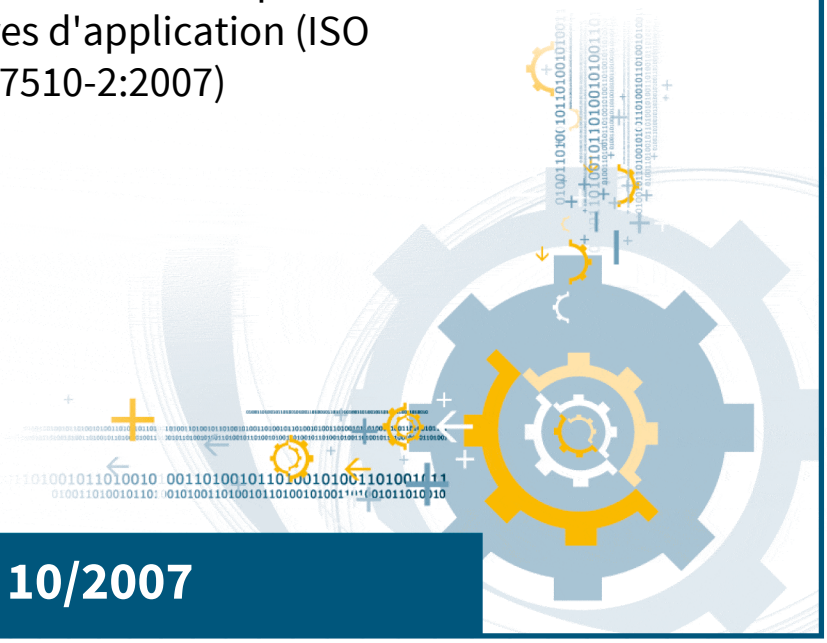
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

# ILNAS-EN 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)



10/2007

**National Foreword**

This European Standard EN ISO 17510-2:2007 was adopted as Luxembourgish Standard ILNAS-EN ISO 17510-2:2007.

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- Participate in the design of standards
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# EUROPEAN STANDARD
# NORME EUROPÉENNE
# EUROPÄISCHE NORM

**EN ISO 17510-2**

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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
ISO 17510-2:2007(E)