

# ILNAS

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

## ILNAS-EN ISO 17510:2020

### **Medical devices - Sleep apnoea breathing therapy - Masks and application accessories (ISO 17510:2015)**

Medizinische Geräte - Schlafapnoe-  
Atemtherapie - Masken und  
Anwendungszubehör (ISO 17510:2015)

Dispositifs médicaux - Thérapie  
respiratoire de l'apnée du sommeil -  
Masques et accessoires d'application  
(ISO 17510:2015)

02/2020



## National Foreword

This European Standard EN ISO 17510:2020 was adopted as Luxembourgish Standard ILNAS-EN ISO 17510:2020.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

<https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html>

### **THIS PUBLICATION IS COPYRIGHT PROTECTED**

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

ILNAS-EN ISO 17510:2020

EUROPEAN STANDARD **EN ISO 17510**

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2020

---

ICS 11.040.10

English Version

**Medical devices - Sleep apnoea breathing therapy - Masks  
and application accessories (ISO 17510:2015)**

Dispositifs médicaux - Thérapie respiratoire de l'apnée  
du sommeil - Masques et accessoires d'application (ISO  
17510:2015)

Medizinische Geräte - Schlafapnoe-Atemtherapie -  
Masken und Anwendungszubehör (ISO 17510:2015)

This European Standard was approved by CEN on 11 November 2019.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

---

<b>Contents</b>	<b>Page</b>
<b>European foreword.....</b>	<b>3</b>

## European foreword

The text of ISO 17510:2015 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 17510:2020 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 August 2020, and conflicting national standards shall be withdrawn at the latest by August 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 17510-2:2009.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Endorsement notice

The text of ISO 17510:2015 has been approved by CEN as EN ISO 17510:2020 without any modification.

ILNAS-EN-ISO 17510:2015  
**INTERNATIONAL  
STANDARD**

**ISO  
17510**

First edition  
2015-08-01

---

---

**Medical devices — Sleep apnoea  
breathing therapy — Masks and  
application accessories**

*Dispositifs médicaux — Thérapie respiratoire de l'apnée du sommeil  
— Masques et accessoires d'application*



Reference number  
ISO 17510:2015(E)

© ISO 2015



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Ch. de Blandonnet 8 • CP 401  
CH-1214 Vernier, Geneva, Switzerland  
Tel. +41 22 749 01 11  
Fax +41 22 749 09 47  
copyright@iso.org  
www.iso.org

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 Information to be supplied by the MANUFACTURER</b> .....	<b>3</b>
4.1 General.....	3
4.2 Marking on the protective packaging.....	3
4.3 ACCOMPANYING DOCUMENT.....	4
<b>5 Construction requirements</b> .....	<b>5</b>
5.1 MASK connectors.....	5
5.2 Biocompatibility.....	5
5.3 Protection against REBREATHING.....	6
5.3.1 NORMAL CONDITION protection.....	6
5.3.2 SINGLE FAULT CONDITION PROTECTION.....	6
5.4 CLEANING, DISINFECTION, and sterilization.....	6
5.5 Breathing during SINGLE FAULT CONDITION.....	7
5.6 Breathing system filter.....	7
<b>6 Vibration and noise</b> .....	<b>7</b>
<b>Annex A (informative) Particular guidance and rationale</b> .....	<b>8</b>
<b>Annex B (normative) EXHAUST FLOW test procedure</b> .....	<b>12</b>
<b>Annex C (normative) Resistance to flow (pressure drop)</b> .....	<b>14</b>
<b>Annex D (normative) ANTI-ASPHYXIA VALVE pressure testing</b> .....	<b>16</b>
<b>Annex E (normative) Determination of the inspiratory and expiratory resistance under SINGLE FAULT CONDITION</b> .....	<b>18</b>
<b>Annex F (normative) Carbon Dioxide REBREATHING</b> .....	<b>20</b>
<b>Annex G (normative) Vibration and noise</b> .....	<b>23</b>
<b>Annex H (informative) Guide to information to be supplied by the MANUFACTURER</b> .....	<b>25</b>
<b>Annex I (informative) Reference to the essential principles</b> .....	<b>26</b>
<b>Annex J (informative) Terminology — alphabetized index of defined terms</b> .....	<b>28</b>
<b>Bibliography</b> .....	<b>30</b>