SLOVENSKI STANDARD
SIST EN ISO 8359:2009/A1:2012

01-oktober-2012

Naprave za koncentriranje kisika za uporabo v medicini - Varnostne zahteve - Dopolnilo A1 (ISO 8359:1996/Amd 1:2012)

Oxygen concentrators for medical use - Safety requirements - Amendment 1 (ISO 8359:1996/Amd 1:2012)

Sauerstoff-Konzentratoren für medizinische Zwecke - Sicherheitsanforderungen - Änderung 1 (ISO 8359:1996/Amd 1:2012)

Concentrateurs d'oxygène à usage médical - Prescriptions de sécurité - Amendement 1 (ISO 8359:1996/Amd 1:2012)

Ta slovenski standard je istoveten z: **EN ISO 8359:2009/A1:2012**

ICS:

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

SIST EN ISO 8359:2009/A1:2012 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8359:2009/A1

July 2012

ICS 11.040.10

English Version

Oxygen concentrators for medical use - Safety requirements - Amendment 1 (ISO 8359:1996/Amd 1:2012)

Concentrateurs d'oxygène à usage médical - Prescriptions de sécurité - Amendement 1 (ISO 8359:1996/Amd 1:2012)

Sauerstoff-Konzentratoren für medizinische Zwecke - Sicherheitsanforderungen - Änderung 1 (ISO 8359:1996/Amd 1:2012)

This amendment A1 modifies the European Standard EN ISO 8359:2009; it was approved by CEN on 24 July 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 8359:2009/A1:2012: E

Contents

Page

Foreword

This document (EN ISO 8359:2009/A1:2012) 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 January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.

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 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, 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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 8359:1996/Amd 1:2012 has been approved by CEN as a EN ISO 8359:2009/A1:2012 without any modification.

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 one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative 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 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes

Add the following row in Table ZA.1 of EN 8359:2009

10.3	9.3, 12.7.4	

Delete the following rows in Table ZA.1 of EN 8359:2009

6.1 to 6.5	9.3	
10.3	12.7.4	

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

INTERNATIONAL STANDARD

ISO 8359

Second edition
1996-12-15

AMENDMENT 1
2012-07-01

Oxygen concentrators for medical use — Safety requirements

AMENDMENT 1

Concentrateurs d'oxygène à usage médical — Prescriptions de sécurité

AMENDEMENT 1

Reference number
ISO 8359:1996/Amd.1:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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.

Amendment 1 to ISO 8359:1996 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This amendment was prepared to address new information regarding the role of oxygen concentrators in accelerating fires in the home that have been caused by patients smoking while undergoing oxygen therapy. Although these changes cannot prevent such fires, it is hoped that the severity of such fires can be reduced by these changes.