



SLOVENSKI STANDARD
SIST EN ISO 8359:2009/kFprA1:2012
01-junij-2012

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

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

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

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

Ta slovenski standard je istoveten z: EN ISO 8359:2009/FprA1

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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SIST EN ISO 8359:2009/kFprA1:2012 en,fr,de

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

FINAL DRAFT
EN ISO 8359:2009

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April 2012

ICS 11.040.10

English Version

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

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

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

This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 215.

This draft amendment A1, if approved, will modify the European Standard EN ISO 8359:2009. If this draft becomes an amendment, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 8359:2009/FprA1:2012) 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 document is currently submitted to the Unique Acceptance Procedure.

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(s).

Endorsement notice

The text of ISO 8359:2009/FprA1:2012 has been approved by CEN as a EN ISO 8359:2009/FprA1:2012 without any modification.

FINAL
DRAFT

AMENDMENT

ISO
8359:1996
FDAM 1

ISO/TC 121/SC 3

Secretariat: ANSI

Voting begins on:
2012-04-12

Voting terminates on:
2012-06-12

Oxygen concentrators for medical use — Safety requirements

AMENDMENT 1

Concentrateurs d'oxygène à usage médical — Prescriptions de sécurité
AMENDEMENT 1

Please see the administrative notes on page iii

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

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ISO/CEN PARALLEL PROCESSING

This final draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.