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

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

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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.

This draft amendment was established by CEN 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.

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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
COMITÉ EUROPÉEN DE NORMALISATION
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/FDAM 1:2012 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

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

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.