

Oxygen concentrators for medical use — Safety requirements

ICS 11.040.10

National foreword

This British Standard is the UK implementation of EN ISO 8359:2009+A1:2012. It is identical to ISO 8359:1996 incorporating amendment 1:2012. It supersedes BS EN ISO 8359:2009 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted by Technical Committee CH/121, Anaesthetic and respiratory equipment, to Subcommittee CH/121/5, Lung ventilators, tracheal tubes and related equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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English Version

Oxygen concentrators for medical use - Safety requirements
(ISO 8359:1996)

Concentrateurs d'oxygène à usage médical - Prescriptions
de sécurité (ISO 8359:1996)

Sauerstoff-Konzentratoren für medizinische Zwecke -
Sicherheitsanforderungen (ISO 8359:1996)

This European Standard was approved by CEN on 21 March 2009.

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Foreword

The text of ISO 8359:1996 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 8359:2009 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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This document supersedes EN ISO 8359:1996.

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.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

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

Foreword to amendment 1

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.

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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 a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard 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 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 EU Directives

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	1 (1st paragraph), 2, 3	
1.7	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
1.7	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
1.7 1st dash to 4th dash	13.3	
1.7 1st dash to 6th dash	13.4	
1.7 6th dash to 5.8 dash	9.2	
3.1 to 3.8	12.6	
4.1 to 4.8	4, 12.7.1, 12.7.2, 12.7.3, 12.7.4	
4.1 to 7.8	4	
10.1 to 10.6	12.6	
1.6	12.6	
1.7	12.6, 13.1	
1.7 4th dash	7.2	
1.7 5th dash	13.2	
1.7 6th dash	7.2, 8.1, 9.1, 13.6, (except e) and j))	
1.7 7th dash	9.1, 13.6, (except e) and j))	
1.7 8th dash	13.6 (except e and j)	
1.8	12.6	
2.3	4, 5	
5.8	12.5	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
7.1	7.1, 7.2, 12.7.5	
7.2	7.1, 7.3, 9.3	
7.2 a) 2)	7.5	
-	1 (2nd paragraph, 1st dash)	This relevant Essential Requirement is not specifically addressed in this European Standard
-	1 (2nd paragraph, 2nd dash)	This relevant Essential Requirement is not specifically addressed in this European Standard
-	6a	This relevant Essential Requirement is not addressed in this European Standard
7.3	7.6, 8.1	
7.3	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	7.5 (2nd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
-	7.5 (3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
8.1	9.2, 12.8.1, 12.8.2	
8.2	9.2, 12.8.1, 12.8.2	
8.2 2nd dash	7.1, 7.2, 8.1	
8.2 3rd dash	12.4	
9.1	4, 7.5, 9.3, 12.6	
9.2	12.6	
10.3	9.3, 12.7.4	
10.3 1st dash	12.9	
10.3 2nd dash	12.9	
10.4	12.7.4	
11.2	12.3	

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

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
 (according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	EHSR of 2006/42/EC	Qualifying remarks/Notes
-	1.1.4	This relevant EHSR is not addressed in this European Standard
8	1.2.2	This relevant EHSR is not fully addressed in this European Standard
-	1.5.4	This relevant EHSR is not addressed in this European Standard
-	1.6.1	This relevant EHSR is not addressed in this European Standard
-	1.6.2	This relevant EHSR is not addressed in this European Standard
-	1.6.3	This relevant EHSR is not addressed in this European Standard
-	3.6.2	This relevant EHSR is not fully addressed in this European Standard

INTERNATIONAL STANDARD

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Oxygen concentrators for medical use — Safety requirements

Concentrateurs d'oxygène à usage médical — Prescriptions de sécurité



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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.

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.

International Standard ISO 8359 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This second edition cancels and replaces the first edition (ISO 8359:1988), which has been technically revised.

Annexes A to N form an integral part of this International Standard. Annexes P and Q are for information only.