SLOVENSKI STANDARD
SIST EN ISO 15001:2004

01-november-2004

Anestezijska in respiratorna oprema – Združljivost s kisikom (ISO 15001:2003)

Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2003)

Anästhesie- und Beatmungsgeräte - Verträglichkeit mit Sauerstoff (ISO 15001:2003)

Matériel d'anesthésie et respiratoire - Compatibilité avec l'oxygene (ISO 15001:2003)

Ta slovenski standard je istoveten z: EN ISO 15001:2004

ICS:

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

SIST EN ISO 15001:2004 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15001

May 2004

ICS 11.040.10

English version

Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2003)

Matériel d'anesthésie et respiratoire - Compatibilité avec l'oxygène (ISO 15001:2003)

Anästhesie- und Beatmungsgeräte - Verträglichkeit mit Sauerstoff (ISO 15001:2003-

This European Standard was approved by CEN on 23 April 2004.

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 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 Management Centre has the same status as the official versions.

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

The text of ISO 15001:2003 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 15001:2004 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 November 2004, and conflicting national standards shall be withdrawn at the latest by November 2004.

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).

For relationship with EU Directive(s), see informative Annex ZB, which is an integral part of this document.

Details of corresponding International and European standards are given in Annex ZA, which is normative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 15001:2003 has been approved by CEN as EN ISO 15001:2004 without any modifications.

Annex ZA
(normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 14971	2000	Medical devices - Application of risk management to medical devices	EN ISO 14971	2000

Annex ZB
(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.

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 normative clauses of this standard given in Table ZB.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.

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

TABLE ZB.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
All	7.2, 7.3, 9.2, 9.3, 12.7.4	This standard specifies minimum requirements for the oxygen compatibility of materials, components and devices that can come into contect with oxygen in normal or single fault condition.

INTERNATIONAL STANDARD

ISO 15001

First edition
2003-05-15

Anaesthetic and respiratory equipment — Compatibility with oxygen

Matériel d'anesthésie et respiratoire — Compatibilité avec l'oxygène

Reference number
ISO 15001:2003(E)

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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.

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.

ISO 15001 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

Introduction

Oxygen, pure or mixed with other medical gases, is widely used in medical applications. Because patients and clinical personnel are often in close proximity to devices used with oxygen, the risk of serious injury is high if a fire occurs in an oxygen-enriched atmosphere. A common cause of fire is the heat produced by adiabatic compression, and the presence of hydrocarbon and particulate contaminants facilitates ignition. Some combustion products, especially of some non-metals (e.g. plastics, elastomers and lubricants) are toxic and thus patients remote from that equipment who are receiving oxygen from a medical gas pipeline system might be injured when a problem occurs.

Other equipment which is in close proximity to the equipment using oxygen, or that utilizes oxygen as its source of power can be damaged or fail to function properly if there is a problem with the oxygen equipment.

Reduction or avoidance of these risks depends on the choice of appropriate materials and cleaning procedures and correct design and construction of equipment so that it is compatible with oxygen under the conditions of use.

This document establishes recommended minimum criteria for the safe use of oxygen and the design of systems for use in oxygen and oxygen-enriched atmospheres.

Annex F contains rationale statements for some of the requirements of this International Standard. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this International Standard. The clauses and subclauses marked with **R** after their number have corresponding rationale contained in Annex F. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revisions.

It is expected that particular device standards will make reference to this horizontal International Standard but may, if appropriate, strengthen these minimum requirements.

Particular device standards may specify that some requirements of this International Standard may apply for medical gases other than oxygen.

Anaesthetic and respiratory equipment — Compatibility with oxygen

1 R Scope

This International Standard specifies minimum requirements for the oxygen compatibility of materials, components and devices for anaesthetic and respiratory applications which can come in contact with oxygen in normal condition or in single fault condition at gas pressures greater than 50 kPa.

This International Standard is applicable to anaesthetic and respiratory equipment which are within the scope of ISO/TC 121, e.g. medical gas pipeline systems, pressure regulators, terminal units, medical supply units, flexible connections, flow-metering devices, anaesthetic workstations and lung ventilators.

Aspects of compatibility that are addressed by this International Standard include cleanliness, resistance to ignition and the toxicity of products of combustion and/or decomposition.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
adiabatic compression
compression process that occurs without transfer of heat into or out of a system

3.2
auto-ignition temperature
temperature at which a material will spontaneously ignite under specified conditions

3.3
lethal concentration
LC_{50}
concentration of a gas (or a gas mixture) in air administered by a single exposure during a short period of time (24 h or less) to a group of young adult albino rats (males and females) which leads to the death of half of the animals in at least 14 days

[ISO 10298:1995]