# Anesteesia- ja hingamisseadmed. Sobivus hapnikuga kasutamiseks (ISO 15001:2010)

Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2010)



EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

| | |
|---|---|
| Käesolev Eesti standard EVS-EN ISO 15001:2011 sisaldab Euroopa standardi EN ISO 15001:2011 ingliskeelset teksti. | This Estonian standard EVS-EN ISO 15001:2011 consists of the English text of the European standard EN ISO 15001:2011. |
| Standard on kinnitatud Eesti Standardikeskuse 31.10.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas. | This standard is ratified with the order of Estonian Centre for Standardisation dated 31.10.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation. |
| Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 19.10.2011. | Date of Availability of the European standard text 19.10.2011. |
| Standard on kättesaadav Eesti standardiorganisatsioonist. | The standard is available from Estonian standardisation organisation. |



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EUROPEAN STANDARD

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# EN ISO 15001

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English Version

# Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2010)

Matériel d'anesthésie et de réanimation respiratoire - Compatibilité avec l'oxygène (ISO 15001:2010)

Anästhesie- und Beatmungsgeräte - Verträglichkeit mit Sauerstoff (ISO 15001:2010)

This European Standard was approved by CEN on 20 September 2011.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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# Foreword

This document (EN ISO 15001:2011) 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 April 2012, and conflicting national standards shall be withdrawn at the latest by April 2012.

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 supersedes EN ISO 15001:2010.

This edition contains a revised Annex ZA.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

**Endorsement notice**

The text of ISO 15001:2010 has been approved by CEN as EN ISO 15001:2011 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 Medical Devices.

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 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 Medical Devices**

| Clause(s)/subclause(s) of this EN | Essential Requirements (ERs) of Directive 93/42/EEC | Qualifying remarks/Notes |
|---|---|---|
| | | This standard specifies minimum requirements for the oxygen compatibility of materials components and devices that can come into contact with oxygen in normal or single fault condition. All its requirements aim at minimising the risk of fire/oxidation and the consequences to the patients treated by devices connected to the concerned pipeline/devices system. |
| 4, 5, 6 | 7.1 first indent | Risks other than risks to patients resulting from combustion/oxidation are not addressed. |
| 4, 5, 6 | 7.3 | Only for aspects of oxygen compatibility. |
| 4, 5, 6 | 9.2 first indent | Only risks of injury linked with sudden increase of pressure, temperature due to fire are covered. |
| 4, 5, 6 | 9.3 | Only for aspects of oxygen compatibility. |

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

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# 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 some non-metals (e.g. plastics, elastomers and lubricants) are toxic and thus patients remote from that equipment and 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, cleaning procedures and correct design and construction of equipment so that it is compatible with oxygen under the conditions of use.

This International Standard gives recommendations for the selection of materials and the cleaning of components made from them, 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 an asterisk (*) 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 and 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* Scope

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

Additionally, this International Standard gives general guidelines for the selection of materials and components based on available data on their oxygen compatibility, and for carrying out a risk analysis, including addressing the toxicity of products of combustion and/or decomposition.

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 at the design, manufacturing, maintenance and disposal stages.

This International Standard does not apply to biocompatibility.

This International Standard is applicable to anaesthetic and respiratory equipment that is 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.

## 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, *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