

STN	Potrubné systémy medicínálnych plynov. Časť 1: Potrubné systémy na stlačené plyny a vákuum (ISO 7396-1: 2016).	STN EN ISO 7396-1 85 2751
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Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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English Version

Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016)

Systèmes de distribution de gaz médicaux - Partie 1:
Systèmes de distribution de gaz médicaux comprimés
et de vide (ISO 7396-1:2016)

Rohrleitungssysteme für medizinische Gase - Teil 1:
Rohrleitungssysteme für medizinische Druckgase und
Vakuum (ISO 7396-1:2016)

This European Standard was approved by CEN on 7 November 2015.

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European foreword

This document (EN ISO 7396-1:2016) 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of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by March 2019.

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 7396-1:2007.

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 ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 7396-1:2016 has been approved by CEN as EN ISO 7396-1:2016 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one 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 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)/Sub-clause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 7.1, 7.3	
4.3.2	9.3	
4.3.3	7.1	
4.3.4	9.2, 9.3, 12.7.1	
4.3.5	9.3	
4.3.6	7.1, 9.3, 12.7.1	
4.3.7	7.2, 7.6	
4.3.8	9.2	
4.4.1	2, 3	
4.4.2	1, 2, 3, 4	
5.1 to 5.2.9	1, 2, 3, 4, 7.6, 12.8.1, 12.8.2	
5.3.1 to 5.3.3	2, 3, 7.6	
5.3.4	7, 12.7.1	
5.3.5	7, 12.7.1	
5.3.6	7.1, 9.3	
5.3.7	2, 3	
5.4	3	
5.5.1	3, 12.8	
5.5.2.1 to 5.5.2.11	3, 7.2, 12.8	
5.5.2.12	7.6	
5.5.2.13	3, 9.2	
5.5.2.14	12.7.2	
5.5.2.15	3, 7.2	
5.5.3	3, 7.2, 7.6, 12.8	

5.6	2, 3, 7.2, 7.3, 7.6, 9.3, 12.8	
5.7.1 to 5.7.7	3, 8.1, 12.8.1	
5.7.8 to 5.7.9	7,6, 8.1	
5.7.10	12.7.2	
5.7.11	7.2	
5.7.12	3, 7.2, 7.6	
5.7.13	3, 9.3	
5.7.14	3, 9.3	
5.7.15	3, 12.8	
5.8 to 5.10	2, 3	
6	1, 2, 3, 4, 12.3, 12.8.1, 12.8.2, 12.9	
7	1, 2, 3	
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7.2.6	9.2	
7.3	2,3,4	
7.4	2, 3, 12.8	
8	1, 2	
9	9.1, 12.7.4, 13.6 c)	
9.3	9.2, 12.5, 12.6	
10	13.2	
11	1, 2, 3, 4, 9	
11.1.5	12.6	
12.1 to 12.4	1, 2, 3	
12.5.1	9.3, 12.7.1, 9.2	
12.5.2	7.5, 9.3, 12.7.1, 9.2	
12.6.1	7.5, 12.7.1	
12.6.2 to 12.6.9	2, 3, 7.5, 12.8	
12.6.10	7.2	
12.6.11	7.2	
12.6.12	7.2	
12.6.13	7.2	
12.6.14	7.2	
12.6.15 to 12.6.16	12.7.4, 12.8.1	
13	4, 13.1, 13.3, 13.6 c), 13.6 d), 13.6 e), 13.6 k), 13.6 l), 13.6 m), 13.6 n), 13.6 q)	

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

**Medical gas pipeline systems —
Part 1:
Pipeline systems for compressed
medical gases and vacuum**

Systèmes de distribution de gaz médicaux —

Partie 1: Systèmes de distribution de gaz médicaux comprimés et de vide



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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

This third edition cancels and replaces the second edition (ISO 7396-1:2007) and ISO 10083:2006, which have been technically revised. It also incorporates the Amendments ISO 7396-1:2007/Amd1:2010, ISO 7396-1:2007/Amd2:2010, and ISO 7396-1:2007/Amd3:2013.

ISO 7396 consists of the following parts, under the general title *Medical gas pipeline systems*:

- *Part 1: Pipeline systems for compressed medical gases and vacuum*
- *Part 2: Anaesthetic gas scavenging disposal systems*

Introduction

Many healthcare facilities use pipeline systems to deliver medical gases and to provide vacuum to areas where they are used in patient care or to power equipment such as ventilators and surgical tools.

This part of ISO 7396 specifies requirements for pipeline systems for gases for medicinal use, medical device gases, gases for driving surgical tools and vacuum. It is intended for use by those persons involved in the design, construction, inspection and operation of healthcare facilities treating human beings. Those persons involved in the design, manufacture and testing of equipment intended to be connected to these pipeline systems should also be aware of the contents of this part of ISO 7396.

This part of ISO 7396 seeks to ensure that medical gas pipelines contain only the specific gas (or vacuum) intended to be supplied. For this reason, gas-specific components are used for terminal units and for other connectors which are intended to be used by the operator. In addition, each system is tested and certified to contain only the specific gas (or vacuum).

The objectives of this part of ISO 7396 are to ensure the following:

- a) non-interchangeability between different pipeline systems by design, installation and testing;
- b) continuous supply of gases and vacuum at specified quality, pressures and specified flows by providing appropriate sources;
- c) use of suitable materials;
- d) cleanliness of components;
- e) correct installation;
- f) provision of monitoring and alarm systems;
- g) correct marking of the pipeline system;
- h) testing and commissioning;
- i) quality of the gases delivered by the pipeline system;
- j) correct operational management;
- k) safety features of the sources to ensure the quality of the gases according to specification.

The responsibility for the quality of the medical gas supplied via the medical gas pipeline system should be assigned to a nominated person within the healthcare facility. This role would usually be assigned to the Head Pharmacist, who may in turn nominate other responsible person(s) on site to manage the day-to-day requirements.

Where the medical gas is supplied by a third party (in some jurisdictions under licence from the national, regional or local regulatory body), the supplier is responsible for ensuring that the medical gas as delivered meets the relevant specification requirements. In this case, the healthcare facility is responsible under local regulations for ensuring that the product meets the specifications as ordered, that the product administered to patients is not adulterated and complies with specifications and regulations, and that the product manufacturer is informed immediately of any undesirable effects or defects in the quality of the product.

Where the healthcare facility manufactures the gas on site, e.g. for medical air produced by air compressor systems, medical air produced by proportioning systems or oxygen 93 produced by oxygen concentrator systems, the healthcare facility is responsible for all aspects of the medical gas quality.

NOTE Vacuum is also the responsibility of the healthcare facility.

[Annex G](#) provides guidance for the assignment of responsibility for production and quality control of the gases and vacuum.

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National, regional or local regulatory bodies may require the manufacture of medical gases on the healthcare facility site to be licenced.

[Annexes G and K](#) provide some guidance as to how the quality of the gas should be managed to maintain patient safety at the highest level.

[Annex H](#) contains rationale statements for some of the requirements of this part of ISO 7396. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this part of ISO 7396. The clauses and subclauses marked with (*) after their number have a corresponding rationale in [Annex H](#).

Medical gas pipeline systems —

Part 1:

Pipeline systems for compressed medical gases and vacuum

1 (*) Scope

This part of ISO 7396 specifies requirements for design, installation, function, performance, testing, commissioning and documentation of pipeline systems used in healthcare facilities for the following:

- oxygen;
- nitrous oxide;
- medical air;
- carbon dioxide;
- oxygen/nitrous oxide mixtures (see Note 1);
- helium/oxygen mixtures;
- (*) oxygen 93;
- gases and gas mixtures classified as medical device, gases delivered to medical devices or intended for medical purposes or gases and gas mixtures for medicinal use not specified above;
- air for driving surgical tools;
- nitrogen for driving surgical tools;
- vacuum.

NOTE 1 Regional or national regulations may prohibit the distribution of oxygen/nitrous oxide mixtures in medical gas pipeline systems.

NOTE 2 Anaesthetic gas scavenging disposal systems are covered in ISO 7396-2.

This part of ISO 7396 includes requirements for supply systems, pipeline distribution systems, control systems, monitoring and alarm systems and non-interchangeability between components of different gas/vacuum systems.

This part of ISO 7396 specifies safety requirements for pipeline systems used in healthcare facilities, both public and private. It applies to all facilities providing healthcare services regardless of type, size, location or range of services, including, but not limited to:

- a) acute care healthcare facilities;
- b) internal patient continuing care healthcare facilities;
- c) long-term care facilities;
- d) community-based providers;
- e) ambulatory and external patient care clinics (e.g. day surgery, endoscopy clinics and doctors' offices).

NOTE 3 This part of ISO 7396 may also be used as reference for pipeline systems for medical gases and vacuum intended to be installed in places other than healthcare facilities.

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This part of ISO 7396 applies to the following different types of oxygen supply systems:

- supply systems in which all sources of supply deliver oxygen; in this case the concentration of the oxygen will be greater than 99%;
- supply systems in which all sources of supply deliver oxygen 93; in this case the concentration of the oxygen may vary between 90% and 96%;

NOTE 4 A mixture of oxygen 93 and oxygen may be delivered by a medical gas supply system. In this case the concentration of the gas can vary between 90% and >99%.

This part of ISO 7396 also applies to:

- extensions of existing pipeline distribution systems;
- modifications of existing pipeline distribution systems;
- modifications or replacement of supply systems or sources of supply.

Oxygen concentrators for domiciliary use are excluded from the scope of this part of ISO 7396.

NOTE 5 Requirements for oxygen concentrators for domiciliary use are specified in ISO 80601-2-69.

(*) EN 14931 defines additional requirements for hyperbaric application, in particular for flows and pressures of compressed air required to pressurize the hyperbaric chamber and to drive other connected services. Also included are requirements for oxygen and other treatment gases administered to patients.

This part of ISO 7396 does not apply to vacuum systems intended to be used in dentistry.

This part of ISO 7396 does not apply to filling systems for transportable cylinders and transportable cylinder bundle systems.

2 Normative references

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

NOTE Additional references are listed in the Bibliography.

ISO 3746:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 8573-1:2010, *Compressed air — Part 1: Contaminants and purity classes*

ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 10524-2:2005, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

ISO 11197:2004, *Medical supply units*

ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15001:2010, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 17672:2010, *Brazing — Filler metals*

ISO 18082:2014, *Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*

ISO 21969:2009, *High-pressure flexible connections for use with medical gas systems*

ISO 29463-1:2011, *High-efficiency filters and filter media for removing particles in air — Part 1: Classification, performance testing and marking*

ISO 80601-2-69:2014, *Medical electrical equipment — Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment*

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

EN 286-1:1998, *Simple unfired pressure vessels designed to contain air or nitrogen — Part 1: Pressure vessels for general purposes*

EN 1041:2008, *Information supplied by the manufacturer of medical devices*

EN 1254-1:1998, *Copper and copper alloys - Plumbing fittings - Fittings with ends for capillary soldering or capillary brazing to copper tubes*

EN 1254-4:1998, *Copper and copper alloys - Plumbing fittings - Fittings combining other end connections with capillary or compression ends*

EN 13348:2008, *Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN