ILNAS

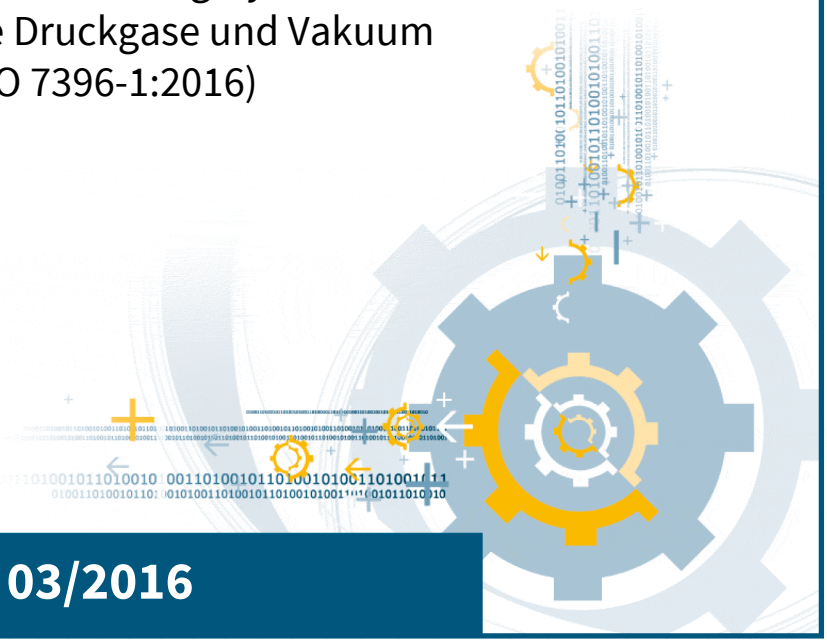
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 7396-1:2016

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)



03/2016

National Foreword

This European Standard EN ISO 7396-1:2016 was adopted as Luxembourgish Standard ILNAS-EN ISO 7396-1:2016.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 7396-1

March 2016

ICS 11.040.10

Supersedes EN ISO 7396-1:2007

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.

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

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

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

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Ref. No. EN ISO 7396-1:2016 E

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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.

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

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	
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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	
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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.

INTERNATIONAL STANDARD

ISO 7396-1

Third edition
2016-02-15

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

Reference number
ISO 7396-1:2016(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.

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.

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.