

Geregistreeerde Belgische norm

NBN EN ISO 7396-1/A2

1e uitg., maart 2010

Normklasse: S 30

Pijpleidingsystemen voor medische gassen - Deel 1: Pijpleidingsystemen voor medische gassen onder druk en vacuüm - Amendement 2 (ISO 7396-1:2007/Amd 2:2010)

Systèmes de distribution de gaz médicaux - Partie 1: Systèmes de distribution de gaz médicaux comprimés et de vide - Amendement 2 (ISO 7396-1:2007/Amd 2:2010)

Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum - Amendment 2 (ISO 7396-1:2007/Amd 2:2010)

Toelating tot publicatie: 19 maart 2010

Deze Europese norm EN ISO 7396-1/A2:2010 heeft de status van een Belgische norm.

Deze Europese norm bestaat in drie officiële versies (Duits, Engels, Frans).



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**norme belge
enregistrée**

NBN EN ISO 7396-1/A2

1e éd., mars 2010

Indice de classement: S 30

Systèmes de distribution de gaz médicaux - Partie 1: Systèmes de distribution de gaz médicaux comprimés et de vide - Amendement 2 (ISO 7396-1:2007/Amd 2:2010)

Pijpleidingsystemen voor medische gassen - Deel 1: Pijpleidingsystemen voor medische gassen onder druk en vacuüm - Amendement 2 (ISO 7396-1:2007/Amd 2:2010)

Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum - Amendment 2 (ISO 7396-1:2007/Amd 2:2010)

Autorisation de publication: 19 mars 2010

La présente norme européenne EN ISO 7396-1/A2:2010 a le statut d'une norme belge.

La présente norme européenne existe en trois versions officielles (allemand, anglais, français).

English Version

Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum - Amendment 2 (ISO 7396-1:2007/Amd 2:2010)

Systèmes de distribution de gaz médicaux - Partie 1:
Systèmes de distribution de gaz médicaux comprimés et
de vide - Amendement 2 (ISO 7396-1:2007/Amd 2:2010)

Rohrleitungssysteme für medizinische Gase - Teil 1:
Rohrleitungensysteme für medizinische Druckgase und
Vakuum - Änderung 2 (ISO 7396-1:2007/Amd 2:2010)

This amendment A2 modifies the European Standard EN ISO 7396-1:2007; it was approved by CEN on 30 January 2010.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

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



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Foreword

This document (EN ISO 7396-1:2007/A2:2010) 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 Amendment to the European Standard EN ISO 7396:2007 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2010, and conflicting national standards shall be withdrawn at the latest by August 2010.

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 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 7396-1:2007/Amd 2:2010 has been approved by CEN as a EN ISO 7396-1:2007/A2:2010 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	7.2, 7.6	
4.3.9	9.2	
5.5.2.12	3, 9.2	
4.4.1	2, 3	
4.4.2	1, 2, 3, 4	
5.1 to 5.2.7	1, 2, 3, 4, 7.6, 12.8.1, 12.8.2	
5.2.8	3	
5.3.1 to 5.3.4	2, 3, 7.6	
5.3.5	7, 12.7.1	
5.3.6	7, 12.7.1	
5.3.7	7.1, 9.3	
5.3.8	7.1	
5.4	3	
5.5.1	3, 12.8	
5.5.2.1 to 5.5.2.10	3, 7.2, 12.8	
5.5.2.11	7.6	
5.5.2.13	12.7.2	
5.5.3	3, 7.2, 7.6, 12.8	
5.6	3, 7.2, 7.6, 9.3, 12.8	

Clause(s)/Sub-clause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
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	
5.8 to 5.10	2, 3	
6	1, 2, 3, 4, 12.3, 12.8.1, 12.8.2, 12.9	
7	1, 2, 3	
7.1	9.3, 12.7.1	
7.2.1 to 7.2.4	2, 3	
7.2.5	9.2	
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	
11.1.3	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)	

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

Second edition
2007-04-01

AMENDMENT 2
2010-02-01

Medical gas pipeline systems —

Part 1:

Pipeline systems for compressed medical gases and vacuum

AMENDMENT 2

Systèmes de distribution de gaz médicaux —

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

AMENDEMENT 2



Reference number
ISO 7396-1:2007/Amd.2:2010(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.

Amendment 2 to ISO 7396-1:2007 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

Medical gas pipeline systems —

Part 1: Pipeline systems for compressed medical gases and vacuum

AMENDMENT 2

Page 13, 5.5.1.3

Replace the text of 5.5.1.3 by the following text:

Medical air and air for driving surgical tools shall not be provided for applications such as general workshop use, motor repair workshop use, spray painting, tyre inflation, reservoirs for pressurization of hydraulic fluids, sterilizing systems and/or pneumatic control of air conditioning. Medical air and air for driving surgical tools shall also not be provided for any other application which can impose unforeseen demands and could compromise the availability and/or quality of air for the intended purposes.



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