SLOVENSKI STANDARD
SIST EN ISO 7396-1:2007/A2:2010

01-junij-2010

Sistemi napeljav za medicinske pline - 1. del: Napeljave za stisnjene medicinske pline in podtlak - Dopolnilo A2 (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)

Rohrleitungssysteme für medizinische Gase - Teil 1: Rohrleitungenssyteme für medizinische Druckgase und Vakuum - Änderung 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)

Ta slovenski standard je istoveten z: **EN ISO 7396-1:2007/A2:2010**

ICS:

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

SIST EN ISO 7396-1:2007/A2:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 7396-1:2007/A2

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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)

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Rohrleitungssysteme für medizinische Gase - Teil 1: Rohrleitungenssyteme 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.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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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	
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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	
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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	
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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 1
2010-01-15

Medical gas pipeline systems —

Part 1: Pipeline systems for compressed medical gases and vacuum

AMENDMENT 1: Requirements for terminal units for vacuum fitted on medical supply units with operator-adjustable portions and connected to the pipeline through flexible hoses

Systèmes de distribution de gaz médicaux —

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

AMENDEMENT 1: *Exigences relatives aux prises murales pour le vide montées sur des gaines techniques médicales munies de sections réglables par l'opérateur et raccordées aux canalisations par des flexibles*

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