

# **Geregistreeerde Belgische norm**

## **NBN EN ISO 7396-1/A1**

1e uitg., maart 2010

**Normklasse: S 30**

### **Pijpleidingsystemen voor medische gassen - Deel 1: Pijpleidingsystemen voor medische gassen onder druk en vacuüm - Amendement 1: Eisen voor vacuüm afnamepunten passend op voedingseenheden voor medische toepassing met door de bediener instelbare gedeelten en verbonden met de pijpleiding door flexibele slangen (ISO 7396-1:2007/Amd 1:2010)**

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 (ISO 7396-1:2007/Amd 1:2010)

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 (ISO 7396-1:2007/Amd 1:2010)

**Toelating tot publicatie: 19 maart 2010**

Deze Europese norm EN ISO 7396-1/A1:2010 heeft de status van een Belgische norm.

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

**norme belge  
enregistrée**

**NBN EN ISO 7396-1/A1**

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 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 (ISO 7396-1:2007/Amd 1:2010)**

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**Autorisation de publication: 19 mars 2010**

La présente norme européenne EN ISO 7396-1/A1:2010 a le statut d'une norme belge.

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



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## English Version

**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 (ISO 7396-1:2007/Amd 1:2010)**

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Rohrleitungssysteme für medizinische Gase - Teil 1: Rohrleitungssysteme für medizinische Druckgase und Vakuum - Änderung 1: Anforderungen an Entnahmestellen für Vakuum, die an medizinische Versorgungseinheiten mit vom Anwender einstellbaren Abschnitten angebracht und durch flexible Schläuche mit der Rohrleitung verbunden sind (ISO 7396-1:2007/Amd 1:2010)

This amendment A1 modifies the European Standard EN ISO 7396-1:2007; it was approved by CEN on 9 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.

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## Foreword

This Amendment (EN ISO 7396-1:2007/A1:2010) 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 July 2010, and conflicting national standards shall be withdrawn at the latest by July 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 1:2010 has been approved by CEN as a EN ISO 7396-1:2007/A1:2010 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 a 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 and 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.

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

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## 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*



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

Page 33, 12.6.4

Add the following text after Table 4:

For terminal units for vacuum fitted on medical supply units with operator-adjustable portions (e.g. ceiling pendants) and connected to the pipeline through flexible hoses, the pressure change shall be such as to limit the pressure measured at the terminal unit with the test flow rate of 25 l/min to not more than 60 kPa absolute pressure.



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