EESTI STANDARD EVS-EN ISO 7396-2:2007

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Meditsiinilise gaasi torusüsteemid. Osa 2: Anesteetiliste gaaside evakuatsiooni- ja kahjutustamissüsteemid

Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 7396-2:2007 sisaldab Euroopa standardi EN ISO 7396-2:2007 ingliskeelset teksti. Käesolev dokument on jõustatud 21.06.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 7396-2:2007 consists of the English text of the European standard EN ISO 7396-2:2007. This document is endorsed on 21.06.2007 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This part of ISO 7396 specifies requirements for the design, installation, function, performance, documentation, testing and commissioning of anaesthetic gas scavenging disposal systems, to ensure patient safety and to minimize exposure of the operator and other persons to anaesthetic gases and vapours. It includes requirements for the power device, pipeline system, performance, non-interchangeability between key components and avoidance of cross connections between anaesthetic gas scavenging (AGS) disposal systems and medical gas and vacuum pipeline systems.	**Scope:** This part of ISO 7396 specifies requirements for the design, installation, function, performance, documentation, testing and commissioning of anaesthetic gas scavenging disposal systems, to ensure patient safety and to minimize exposure of the operator and other persons to anaesthetic gases and vapours. It includes requirements for the power device, pipeline system, performance, non-interchangeability between key components and avoidance of cross connections between anaesthetic gas scavenging (AGS) disposal systems and medical gas and vacuum pipeline systems.

ICS 11.040.10

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Eesti Standardikeskusele kuulub standardite reprodutseerimis- ja levitamisõigus

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7396-2

April 2007

ICS 11.040.10

Supersedes EN 737-2:1998

English Version

Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)

Réseaux de distribution de gaz médicaux - Partie 2: Réseaux d'évacuation de gaz d'anesthésie non réutilisables (ISO 7396-2:2007)

Rohrleitungssysteme für medizinische Gase - Teil 2: Entsorgungssysteme von Anästhesiegas-Fortleitungssystemen (ISO 7396-2:2007)

This European Standard was approved by CEN on 15 March 2007.

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 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 Management Centre has the same status as the official versions.

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Foreword

This document (EN ISO 7396-2:2007) has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment".

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 October 2007, and conflicting national standards shall be withdrawn at the latest by April 2009.

This document supersedes EN 737-2:1998.

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, 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.

Annex ZA
(informative)

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

This International 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 Medical devices.

Once this standard is cited in the Official Journal of the European Communities 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 International Standard and Directive 93/42/EEC

Clause(s)/Sub-clause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4.1	1	
4.2	2	
4.3	2	
4.3.1	4, 7.1, 7.3, 9.2, 9.3	
4.3.2	4, 7.1, 7.3, 9.2, 9.3	
4.3.3	2	
4.3.4	4, 7.1, 9.3	
4.3.5	4, 7.1, 7.3, 9.3	
4.3.6	5	
5.1	1, 2, 3	
5.2	3, 9.3, 12.8.2	
5.3	3, 4	
5.4	3, 4	
5.5	9.2, 9.3	
5.6	9.2, 9.3	
6	2, 12.2, 12.3	
7	1, 2	
7.1	2	
7.2	2	
8.1	1, 3, 9.1, 12.8.2	
8.2	1, 3, 9.1, 12.8.2	
9	9.1, 12.7.4	
10	13.2	
11	1, 2, 3	
11.1	2	
11.2	9.2	
11.3 – 11.11	2, 9.2, 12.7.1	

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Clause(s)/Sub-clause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
11.12	4, 7.2, 7.5	
11.13	7.2, 7.5, 7.6	
12	1, 2, 3	
12.4.1	7.2, 7.5	
12.4.2	9.2, 12.6, 12.7.1, 13.2	
12.4.3	9.1, 12.7.4	
12.4.4	2, 3, 9.2	
12.4.5	3, 12.8.2	
12.4.6	3	
12.4.7	2, 12.2, 12.3	
12.4.8	4, 7.2, 7.5, 7.6	
12.4.9	9.1, 12.7.4	
13	9.1, 13.1, 13.3 a), 13.3 i), 13.3 j), 13.6 a), 13.6 c), 13.6 d)	

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

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INTERNATIONAL STANDARD

ISO 7396-2

Second edition
2007-04-01

Medical gas pipeline systems —

Part 2: Anaesthetic gas scavenging disposal systems

Réseaux de distribution de gaz médicaux —

Partie 2: Réseaux d'évacuation de gaz d'anesthésie non réutilisables

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Reference number
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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.

ISO 7396-2 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 7396-2:2000), which has been technically revised.

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*

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Introduction

Anaesthetic gas scavenging systems (AGSS) are used to reduce occupational exposure to anaesthetic gases and vapours.

The anaesthetic gas scavenging system comprises three main parts:

— a transfer system,

— a receiving system, and

— a disposal system.

A schematic diagram of typical anaesthetic gas scavenging systems is shown in Figure 1. Requirements for receiving systems and transfer systems are specified in ISO 8835-3. Type-specific connections for terminal units are specified in ISO 9170-2. In this part of ISO 7396, specifications and test procedures are given to ensure compatibility between the components of the system.

This part of ISO 7396 specifies requirements for pipelines for anaesthetic gas scavenging systems for anaesthetic gases and vapours. It is intended for use by those persons involved in the design, construction, inspection and operation of healthcare facilities treating human beings. It is advisable that those persons involved in the design, manufacture and testing of equipment intended to be connected to pipeline systems also be aware of the contents of this part of ISO 7396.

Specific components are used for scavenging terminal units and for other connectors which are intended to be used by the operator. In addition, the system is tested and certified to operate at safe flows and without leakage. It is also intended to address issues of patient safety.

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

a) avoidance of cross connections between different pipeline systems;

b) continuity of function of the system;

c) use of suitable materials;

d) cleanliness of components;

e) correct installation;

f) provision of indicating system(s);

g) correct marking of the pipeline system and components;

h) testing, commissioning and certification;

i) correct operational management.

Annex E 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 in this part of ISO 7396. The clauses and subclauses marked with (*) after their number have corresponding rationale contained in Annex E.

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Medical gas pipeline systems —

Part 2: Anaesthetic gas scavenging disposal systems

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1 Scope

This part of ISO 7396 specifies requirements for the design, installation, function, performance, documentation, testing and commissioning of anaesthetic gas scavenging disposal systems to ensure patient safety and to minimize exposure of the operator and other persons to anaesthetic gases and vapours. It includes requirements for the power device, pipeline system, performance, non-interchangeability between key components and avoidance of cross connections between anaesthetic gas scavenging (AGS) disposal systems and medical gas and vacuum pipeline systems.

NOTE In this part of ISO 7396, the term “pipeline” refers exclusively to pipelines that are part of a dedicated anaesthetic gas scavenging system (AGSS).

This part of ISO 7396 is applicable only to those disposal systems intended to be connected via AGSS terminal units conforming to ISO 9170-2 and to AGSS receiving systems conforming to ISO 8835-3.

This part of ISO 7396 also applies to:

— extensions of existing AGSS disposal systems;

— modifications of existing AGSS disposal systems;

— modifications or replacement of power devices.

2 Normative references

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

ISO 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8835-3:—[1)], *Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

ISO 9170-2, *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems*

1) To be published. (Revision of ISO 8835-3:1997.)

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

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

EN 1041, *Information supplied by the manufacturer with medical devices*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
AGSS socket
female part of a terminal unit which is either integral or attached to the base block by a type-specific interface, and which contains the type-specific connection point

3.2
AGSS terminal unit
inlet assembly in an AGSS at which the operator makes connections and disconnections

3.3
AGSS terminal unit base block
part of an AGSS terminal unit which is attached to the pipeline disposal system

3.4
AGSS type 1 terminal unit
connection point between the receiving system and the disposal system at which an operator makes connections and disconnections

See Figure 1.

3.5
AGSS type 1H terminal units
AGSS type 1 terminal unit to be used in high-flow disposal systems

3.6
AGSS type 1L terminal units
AGSS type 1 terminal unit to be used in low-flow disposal systems

3.7
AGSS type 2 terminal unit
connection point between the power device or the disposal hose and the remainder of the disposal system at which an operator makes connections and disconnections

See Figure 1.

3.8
AGSS type-specific
having characteristics which prevent interchangeability and thereby allow assignment to one AGSS type only

3.9
AGSS type-specific connection point
part of the AGSS socket which is the receptor for an AGSS type-specific probe

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