National Standards Authority of Ireland

IRISH STANDARD

I.S. EN ISO 7396-2:2007

ICS 11.040.10

National Standards
Authority of Ireland
Glasnevin, Dublin 9
Ireland
Tel: +353 1 807 3800
Fax: +353 1 807 3838
http://www.nsai.ie

Sales
http://www.standards.ie

MEDICAL GAS PIPELINE SYSTEMS - PART 2: ANAESTHETIC GAS SCAVENGING DISPOSAL SYSTEMS (ISO 7396-2:2007)

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on:
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EUROPEAN STANDARD

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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.

CEN members are the national standards bodies of 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.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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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 October 2007.

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	

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.