National Standards Authority of Ireland
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IRISH STANDARD

I.S. EN ISO 23328-2:2008

ICS 11.040.10

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BREATHING SYSTEM FILTERS FOR ANAESTHETIC AND RESPIRATORY USE - PART 2: NON-FILTRATION ASPECTS (ISO 23328-2:2002)

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EUROPEAN STANDARD

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Supersedes EN 13328-2:2002

English Version

Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects (ISO 23328-2:2002)

Filtres pour matériel d'anesthésie et de réanimation respiratoire - Partie 2: Aspects autres que la filtration (ISO 23328-2:2002)

Filter für Atemsysteme zur Anwendung bei Anästhesie und Beatmung - Teil 2: Aspekte, die nicht die Filtration betreffen (ISO 23328-2:2002)

This European Standard was approved by CEN on 24 February 2008.

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

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Foreword

The text of ISO 23328-2:2002 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 23328-2:2008 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

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 September 2008, and conflicting national standards shall be withdrawn at the latest by September 2008.

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 supersedes EN 13328-2:2002.

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 EC Directive(s).

For relationship with EC 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 the United Kingdom.

Endorsement notice

The text of ISO 23328-2:2002 has been approved by CEN as a EN ISO 23328-2:2008 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC 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 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 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 — Correspondence between this European Standard and Directive (Add the reference and title of the Directive)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC Medical devices	Qualifying remarks/Notes
4	1, 2, 3, 4, 7.5, 9.1	
5	3, 4, 7.5, 7.6	
6	2, 5, 7.2, 8.1, 8.3, 8.4, 8.5	
7	13.1	
7.1	13.2	
7.2	13.1, 13.2, 13.3j), 13.6c)	
7.3	13.3a), b), c), d), e), i), 13.4, 13.5	
7.3c)	8.7, 13.3c)	
7.4	13.3b), f)	
8	13.1, 13.6a), b)	
8a)	13.6d)	
8f)	13.6f), m)	
8g)	8.7, 13.3m), 13.6d), g), h), i)	
8i)	13.6n)	
8k)	13.6c)	

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