Irish Standard
I.S. EN ISO 23328-2:2009

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

I.S. EN ISO 23328-2:2009

Incorporating amendments/corrigenda issued since publication:

This document replaces:	*This document is based on:*	*Published:*
I.S. EN ISO 23328-2:2008	EN ISO 23328-2:2009 EN ISO 23328-2:2008	11 March, 2009 18 June, 2008

This document was published under the authority of the NSAI and comes into effect on:
11 May, 2009

ICS number:
11.040.10

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Price Code:
F

Údarás um Chaighdeáin Náisiúnta na hÉireann

I.S. EN ISO 23328-2:2009

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23328-2

March 2009

ICS 11.040.10

Supersedes EN ISO 23328-2:2008

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 2009.

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: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 23328-2:2009: E

Contents

Page

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 23328-2:2009 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 2009, and conflicting national standards shall be withdrawn at the latest by March 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 supersedes EN ISO 23328-2:2008.

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.

For relationship with EC 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, 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 23328-2:2009 without any modification.

This page is intentionally left BLANK.

I.S. EN ISO 23328-2:2009

INTERNATIONAL STANDARD

ISO 23328-2

First edition
2002-10-15

Breathing system filters for anaesthetic and respiratory use —

Part 2: Non-filtration aspects

Filtres pour matériel d'anesthésie et de réanimation respiratoire —

Partie 2: Aspects autres que filtration

Reference number
ISO 23328-2:2002(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Contents

Page

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 3.

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 part of ISO 23328 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 23328-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

ISO 23328 consists of the following parts, under the general title *Breathing system filters for anaesthetic and respiratory use*:

— *Part 1: Salt test method to assess filtration performance*

— *Part 2: Non-filtration aspects*

Introduction

This part of ISO 23328 gives requirements for non-filtration aspects of breathing system filters (BSF).

BSF are used to reduce particulates, including microorganisms, in gases delivered to and exhaled from patients.

BSF are exposed to various levels of humidity during clinical use. Exposure of the BSF to humidified air to simulate clinical use forms part of the test method, as it is possible that such exposure can influence the filtration performance of the BSF. A test method to assess filtration performance is found in ISO 23328-1.

Breathing system filters for anaesthetic and respiratory use —

Part 2:
Non-filtration aspects

1 Scope

This part of ISO 23328 specifies requirements for non-filtration aspects of breathing system filters (BSF) intended for anaesthetic and respiratory use, and addresses connection ports, leakage, resistance to flow, packaging, marking and information supplied. The test method is intended for BSF used with a clinical breathing system.

It is not applicable to other types of filter, e.g. those designed to protect vacuum sources or gas sample lines, to filter compressed gases, or to protect test equipment for physiological respiratory measurements.

NOTE A method for assessing filtration performance of BSF is given in ISO 23328-1.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 23328. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 23328 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 11607, *Packaging for terminally sterilized medical devices*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*; Amendment 1:1991 and Amendment 2:1995

3 Terms and definitions

For the purposes of this part of ISO 23328, the following terms and definitions apply:

3.1
breathing system filter
BSF
device intended to reduce transmission of particulates, including microorganisms, in breathing systems