Hingamissüsteemi filtrid tuimastuseks ja respiratoorseks kasutuseks. Osa 2: Mittefiltreerimise aspektid

Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 23328-2:2009 sisaldab Euroopa standardi EN ISO 23328-2:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 23328-2:2009 consists of the English text of the European standard EN ISO 23328-2:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 11.03.2009.	Date of Availability of the European standard text 11.03.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

Võtmesõnad: asf, breathing equipment, data of the manufacturer, definition, definitions, filters, gas filters, leakage, medical technology, medicine, packages, packing, particle filters, rating tests, specification (approval), specifications, terminal aperture, testing

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23328-2

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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

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.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

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 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. - Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 3, 4, 7.5, 9.1	
5	3, 4, 7.5, 7.6	
-	6a	This relevant Essential Requirement is not addressed in this European Standard
5.3	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	7.5 (2nd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
-	7.5 (3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
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	
7.3	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
7.3c)	8.7, 13.3c)	
7.4	13.3b), f)	

7.4	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
8	13.1, 13.6a), b)	
8	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
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 products falling within the scope of this International standard.

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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