# Hingamissüsteemi filtrid tuimastuseks ja respiratoorseks kasutuseks. Osa 1: Soolakatsemeetod filtreerimisjõudluse hindamiseks

Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to asses filtration performance

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

| | |
|---|---|
| Käesolev Eesti standard EVS-EN ISO 23328-1:2008 sisaldab Euroopa standardi EN ISO 23328-1:2008 ingliskeelset teksti. | This Estonian standard EVS-EN ISO 23328-1:2008 consists of the English text of the European standard EN ISO 23328-1:2008. |
| Standard on kinnitatud Eesti Standardikeskuse 19.05.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas. | This standard is ratified with the order of Estonian Centre for Standardisation dated 19.05.2008 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 19.03.2008. | Date of Availability of the European standard text 19.03.2008. |
| Standard on kättesaadav Eesti standardiorganisatsioonist. | The standard is available from Estonian standardisation organisation. |



**ICS** 11.040.10

**Võtmesõnad:** anesthetic equipment, asf, breathing equipment, definition, definitions, filters, gas filters, medical technology, medicine, particle filters, rating tests, specification (approval), specifications, testing

EUROPEAN STANDARD

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# EN ISO 23328-1

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English Version

# Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance (ISO 23328-1:2003)

Filtres pour matériel d'anesthésie et de réanimation respiratoire - Partie 1: Méthode d'essai à l'aide d'une solution saline pour l'évaluation de l'efficacité de filtration (ISO 23328-1:2003)

Filter für Atemsysteme zur Anwendung bei Anästhesie und Beatmung - Teil 1: Prüfverfahren mit Salzpartikeln zur Bewertung der Filterleistung (ISO 23328-1:2003)

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.

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Ref. No. EN ISO 23328-1:2008: E

# Foreword

The text of ISO 23328-1:2003 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 23328-1:2008 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 13328-1:2001.

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 23328-1:2003 has been approved by CEN as a EN ISO 23328-1:2008 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 |
|---|---|---|
| All | | This standard is intended to provide a test method that will allow evaluation of the performance of filters intended for use within clinical breathing systems and will improve comparability of results |

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

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# Introduction

This part of ISO 23328 gives a method of test for assessing the filtration performance of breathing system filters (BSF).

BSF are used to reduce the number of 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 this method (see Annex A), as it is possible that such exposure can influence the filtration performance of the BSF.

In the test, the BSF is challenged with sodium chloride particles of the most penetrating size range, i.e. 0,1 µm to 0,3 µm (see Annex C).

It is recognized that transmission of microorganisms across a filter can occur due to “channeling” and “grow-through”. There are at present no accepted methods to quantify these occurrences. This test method is for comparison purposes only, and has no proven clinical relevance. The results are specific to the test method and no risk factor should be derived from it.

# Breathing system filters for anaesthetic and respiratory use —

# Part 1:
# Salt test method to assess filtration performance



## 1 Scope

This part of ISO 23328 gives a short-term airborne sodium chloride particle challenge test method for assessing the filtration performance of breathing system filters (BSF) intended for the filtration of respired gases.

This part of ISO 23328 is applicable to 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 Non-filtration aspects of BSF are addressed in ISO 23328-2.

## 2 Terms and definitions

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

**2.1**
**breathing system filter**
**BSF**
device intended to reduce transmission of particulates, including microorganisms, in breathing systems

**2.2**
**challenge concentration**
concentration of sodium chloride particles in the airstream as it reaches the BSF

NOTE Challenge concentration is expressed in milligrams per cubic metre.

**2.3**
**penetration concentration**
concentration of sodium chloride particles in the airstream flowing out of the BSF

NOTE Penetration concentration is expressed in milligrams per cubic metre.

**2.4**
**penetration value**
concentration of sodium chloride particles passing through the BSF as a percentage of the concentration in the challenge

**2.5**
**percent filtration efficiency**
100 minus the penetration value