SIST

SLOVENSKI STANDARD

SIST EN ISO 23328-1:2008

01-julij-2008

Nadomeĝļ a:

SIST EN 13328-1:2002

Sistem dihalnih filtrov za anestezijsko in dihalno uporabo - 1. del: Preskusna metoda s soljo za ocenitev uļ inkovitosti filtracije (ISO 23328-1:2003)

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

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 la performance de la filtration (ISO 23328-1:2003)

Ta slovenski standard je istoveten z: **EN ISO 23328-1:2008**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 23328-1:2008 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23328-1

March 2008

ICS 11.040.10

Supersedes EN 13328-1:2001

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

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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.

INTERNATIONAL STANDARD

ISO 23328-1

First edition
2003-08-15

Breathing system filters for anaesthetic and respiratory use —

Part 1: Salt test method to assess filtration performance

Filtres pour matériel d'anesthésie et de réanimation respiratoire — Partie 1: Méthode d'essai saline pour l'évaluation de l'efficacité de filtration

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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 2.

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

ISO 23328-1 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 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.