Meditsiiniline imur. Osa 3: Vaakum- või ülerõhuajamiga imur

Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 10079-3:2014 sisaldab Euroopa standardi EN ISO 10079-3:2014 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 10079-3:2014 consists of the English text of the European standard EN ISO 10079-3:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 07.05.2014.	Date of Availability of the European standard is 07.05.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-3

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Supersedes EN ISO 10079-2:2009

English Version

Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014)

Appareils d'aspiration médicale - Partie 3: Appareils d'aspiration alimentés par une source de vide ou de pression (ISO 10079-3:2014)

Medizinische Absauggeräte - Teil 3: Vakuum- oder druckquellenbetriebene Absauggeräte (ISO 10079-3:2014)

This European Standard was approved by CEN on 15 February 2014.

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-CENELEC 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-CENELEC 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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 10079-3:2014) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by DIN.

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 November 2014, and conflicting national standards shall be withdrawn at the latest by May 2017.

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 10079-2:2009.

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 EU Directive.

For relationship with EU 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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10079-3:2014 has been approved by CEN as EN ISO 10079-3:2014 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 Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive.

NOTE When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and 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, 4.4, 12 t)	7.1	Partly covered There are no requirements for materials apart from a requirement to perform a risk assessment and to disclose the presence of latex. As these devices are only for extracting body fluids toxicity and biological compatibility is not considered a risk.
4.1, 5, 7.5, 7.5.2, 7.7	7.2	
4.1, 4.2, 5	7.3	Only the first part of this ER is covered
7.5.1, 7.5.2	8.1	
4.1, 6.3, 6.5	9.1	
4.1, 10	9.2	Only covered as far as temperature is concerned
7.4	12.7.1	Only covered as far as stability is concerned
7.6	12.7.3	
6.5	12.7.4	
11, 12	13.1	
11.2 a)	13.3 a)	
11.2 b)	13.3 b)	
11.2 c)	13.3 c)	
11.2 d)	13.3 d)	
11.2 e)	13.3 e)	

11.2 f)	13.3 f)	
12 b)	13.4	Partly covered: disclosure of the intended purpose is included in the Instructions for use but not the labelling.
12	13.6a)	Covered for the items in 13.3 a), b), c), f), i) and k)
12 b), c), d), f),g), h), j), k), o), t), u)	13.6 b)	
12 k)	13.6 c)	
12 b), c), d), h), j), v)	13.6 d)	
12 i)	13.6 h)	First two paragraphs only
12 d)	13.6 i)	
12 z)	13.6 q)	

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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