MEDITSIINILINE VAAKUMAPARATUUR. OSA 1: ELEKTRITOITEGA VAAKUMAPARATUUR

Medical suction equipment - Part 1: Electrically powered suction equipment (ISO 10079-1:2015)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 10079-1:2015 sisaldab Euroopa standardi EN ISO 10079-1:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10079-1:2015 consists of the English text of the European standard EN ISO 10079-1:2015.
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 25.11.2015.	Date of Availability of the European standard is 25.11.2015.
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.

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EUROPEAN STANDARD

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EN ISO 10079-1

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English Version

Medical suction equipment - Part 1: Electrically powered suction equipment (ISO 10079-1:2015)

Appareils d'aspiration médicale - Partie 1: Appareils électriques d'aspiration (ISO 10079-1:2015)

Medizinische Absauggeräte - Teil 1: Elektrisch betriebene Absauggeräte (ISO 10079-1:2015)

This European Standard was approved by CEN on 13 May 2015.

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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

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European foreword

This document (EN ISO 10079-1:2015) 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 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 May 2016, and conflicting national standards shall be withdrawn at the latest by November 2018.

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 10079-1:2009.

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(s).

For relationship with EU 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, 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 10079-1:2015 has been approved by CEN as EN ISO 10079-1:2015 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, 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 corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 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 Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.1 Third indent only	4.4	
7.2	5; 7.5	Partly covered There are no requirements for packaging.
7.3 First part only	6.1.3	
7.6	6.2.3; 6.5; 7.5.1; 7.5.2	
8.1	4.2; 5; 7.5.1	
8.7	11.3 c)	
9.1 First sentence only	6.2; 6.3	
9.2	4; 6.1.3	Partly covered Electrical safety is by ref to IEC 60601–1 and risk management by ref to ISO 14971.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
10.1	6.4.6	Partly covered. There are no requirements for the manufacturer to disclose the accuracy of the vacuum level indicator.
10.2	6.4	
10.3	11.3 i)	Covered for volume measurements only
12.1	4	Covered by ref to IEC 60601–1
12.1a)	4	Covered by ref to IEC 60601–1
12.2	4	Covered by ref to IEC 60601–1 although suction equipment is not considered life-support equipment.
12.5	4	Covered by ref to IEC 60601–1 and thereby to IEC 60601–1–2
12.6	4; 6.5	Covered by ref to IEC 60601–1
12.7.1	6.1.3; 7.4	
12.7.2	4	Covered by ref to IEC 60601–1
12.7.3	7.6	
12.7.4	4	Covered by ref to IEC 60601–1
12.7.5	4	Covered by ref to IEC 60601–1
12.8.2 Second sentence only	7.5.3.2	
12.9	11.3 i); j); k); l); m); n); o); p); q); r)	
13.1	11	
13.2	11.2	
13.3a)	11.3 a)	
13.3b)	11.3 b)	
13.3c)	11.3 c)	
13.3d)	11.3 d)	
13.3e)	11.3 e)	
13.3 f)	11.3 f)	
13.3 k)	11.4 c); q); y)	
13.3 l)	11.3 d)	
13.3 m)	11.4 i)	
13.4	11.4 b)	
13.6 a)	11.4	Not covered for the requirement of ER 13.3b)
13.6 b)	11.4 d); e)	

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
13.6 c)	11.4 d) ;k)	
13.6 d)	11.4 d); j); v)	Calibration is not covered
13.6 f)	11.4 x)	
13.6 h) First two paragraphs only	11.4 i)	
13.6 i)	11.4 j)	
13.6 q)	11.4 z)	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

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