SLOVENSKI STANDARD
SIST EN ISO 10079-1:2016

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Nadomešča:
SIST EN ISO 10079-1:2009

Medicinska sukcijska (aspiracijska) oprema - 1. del: Električna sukcijska (aspiracijska) oprema (ISO 10079-1:2015)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 10079-1:2015**

ICS:

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

SIST EN ISO 10079-1:2016 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-1

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Supersedes EN ISO 10079-1:2009

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.

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.

CEN members are the national standards bodies of 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 United Kingdom.

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

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

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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.

INTERNATIONAL STANDARD

ISO 10079-1

Third edition
2015-11-01

Medical suction equipment —

Part 1: Electrically powered suction equipment

Appareils d'aspiration médicale —

Partie 1: Appareils électriques d'aspiration

Reference number
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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 8, *Suction devices for hospital and emergency care use*.

This third edition cancels and replaces the second edition (ISO 10079-1:1999), which has been technically revised.

ISO 10079 consists of the following parts, under the general title *Medical suction equipment*:

— *Part 1: Electrically powered suction equipment*

— *Part 2: Manually powered suction equipment*

— *Part 3: Suction equipment powered from a vacuum or positive pressure gas source*

Annex A forms a normative part of this part of ISO 10079 while Annex B, Annex C, and Annex D are for information only.

Annex B contains rationale statements for some of the requirements of this part of ISO 10079. The clauses and subclauses marked with an asterisk (*) at the beginning of the paragraph have corresponding rationale contained in Annex B included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this part of ISO 10079. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 10079, but will expedite any subsequent revisions.

Annex D illustrates the three parts of ISO 10079 by providing a schematic for typical systems.