SLOVENSKI STANDARD
SIST EN ISO 10079-3:2014

01-julij-2014

Nadomešča:
SIST EN ISO 10079-2:2009
SIST EN ISO 10079-3:2009

Medicinska sukcijska (aspiracijska) oprema - 3. del: Podtlačna ali tlačna sukcijska (aspiracijska) oprema (ISO 10079-3:2014)

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

Medizinische Absauggeräte - Teil 3: Vakuum- oder druckquellenbetriebene Absauggeräte (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)

Ta slovenski standard je istoveten z: **EN ISO 10079-3:2014**

ICS:

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

SIST EN ISO 10079-3:2014 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-3

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ICS 11.040.10

Supersedes EN ISO 10079-3:2009

English Version

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

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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.

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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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 10079-3:2009.

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.

INTERNATIONAL STANDARD

ISO 10079-3

Third edition
2014-05-01

Medical suction equipment —

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

Appareils d'aspiration médicale —

Partie 3: Appareils d'aspiration alimentés par une source de vide ou de pression

Reference number
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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 10079-3:1999), 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 Annexes B, C and 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 (*) after their number 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 in 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.