SLOVENSKI STANDARD
SIST EN ISO 10079-1:2009

01-maj-2009

Nadomeġļa:
SIST EN ISO 10079-1:2000

Medicinska sukcijska (aspiracijska) oprema - 1. del: Elektriļna sukcijska (aspiracijska) oprema - Varnostne zahteve (ISO 10079-1:1999)

Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements (ISO 10079-1:1999)

Medizinische Absauggeräte - Teil 1: Elektrisch betriebene Absauggeräte - Sicherheitsanforderungen (ISO 10079-1:1999)

Appareils d'aspiration médicale - Partie 1: Appareils électriques d'aspiration - Prescriptions de sécurité (ISO 10079-1:1999)

Ta slovenski standard je istoveten z: **EN ISO 10079-1:2009**

ICS:

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

SIST EN ISO 10079-1:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-1

March 2009

ICS 11.040.10

Supersedes EN ISO 10079-1:1999

English Version

Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements (ISO 10079-1:1999)

Appareils d'aspiration médicale - Partie 1: Appareils électriques d'aspiration - Prescriptions de sécurité (ISO 10079-1:1999)

Medizinische Absauggeräte - Teil 1: Elektrisch betriebene Absauggeräte - Sicherheitsanforderungen (ISO 10079-1:1999)

This European Standard was approved by CEN on 24 February 2009.

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.

CEN members are the national standards bodies of 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 United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 10079-1:1999 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 10079-1:2009 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 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 10079-1:1999.

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 Directives.

For relationship with EC Directives, 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 10079-1:1999 has been approved by CEN as a EN ISO 10079-1:2009 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 the New Approach Directive 93/42/EEC on 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.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.

Table ZA.1 - Correspondence between this European Standard and EU Directives

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3, 4, 6	
-	1 (2nd paragraph, 1st dash)	This relevant Essential Requirement is not addressed in this European Standard
-	1 (2nd paragraph, 2nd dash)	This relevant Essential Requirement is not addressed in this European Standard
-	6a	This relevant Essential Requirement is not addressed in this European Standard
6	9.1, 13	
6	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
6.1 e)	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
6 (6.1 p), 6.3 c))	12.9	
6.8.2	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard

Table ZA.1 - Correspondence between this European Standard and EU Directives (continued)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.8.2	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard: covered by EN ISO 13485: 2003, subclause 4.2.3
9	12.6	
10	12.7	
10.1	9.2, 12.7.1	
10.2	9.2, 12.7.1	
10.3	9.2, 12.7.1	
10.4	9.2, 12.7.1	
10.5	9.2, 12.7.1	
10.6	12.7.2, 12.7.3	
11	11	
11.8	12.5	
12	7.1, 9.3	
13.1	12.7.5	
13.2	7.1, 9.3	
13.3	7.2, 7.5, 9.1	
13.3 (44.2)	8.1	
13.3 (44.3)	7.6	
13.3 (44.4)	7.6	
13.3 (44.6)	7.6	
13.3 (44.7) 1	8.1	
13.4	9.2, 12.7.1	

Table ZA.1 - Correspondence between this European Standard and EU Directives (continued)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
13.5	9.2, 12.8	
13.8 (49.2)	8.1	
14.2	12.8.2	
15	1 (1st paragraph), 2, 4	
15 (53.2, 53.3)	5	
15.1	4	
15.2	9.2	
16	1, 2, 3	
16.1	7.3	
16.3	9.1, 9.2	
16.3 (56.5)	12.8.2	
16.3 (56.8)	10.1, 10.2, 10.3, 12.8.2, 12.9	
16.3 (56.11)	12.7.1	
16.3 (56.12)	9.1, 12.7.4	
16.4	9.1, 12.7.4, 12.6, 12.8.1	
16.5	12.7.4	
16.6	2, 3, 12.8.1, 12.9	
16.6 (59.11)	10.1, 10.2, 10.3, 12.9	
16.6 (59.11.2)	9.2, 9.3	
16.6 (59.12)	7.2	
59	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
-	1.1.4	This relevant EHSR is not addressed in this European Standard
-	1.2.2	This relevant EHSR is not addressed in this European standard; only partially covered by EN 60601-1-6 and EN 14971
-	1.5.4	This relevant EHSR is not fully addressed in this European Standard: only partially covered in EN 14971 and EN 62366
-	1.6.1	This relevant EHSR is not addressed in this European Standard
-	1.6.2	This relevant EHSR is not addressed in this European Standard
-	1.6.3	This relevant EHSR is not addressed in this European Standard
-	3.4.5	This relevant EHSR is not addressed in this European Standard
-	3.6.2	This relevant EHSR is not addressed in this European Standard

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 10079-1

Second edition
1999-08-15

Medical suction equipment —

Part 1:
Electrically powered suction equipment — Safety requirements

Appareils d'aspiration médicale —
Partie 1: Appareils électriques d'aspiration — Prescriptions de sécurité

Reference number
ISO 10079-1:1999(E)

Contents

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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 3.

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.

International Standard ISO 10079-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 8, *Suction devices for hospital and emergency care use*.

This second edition cancels and replaces the first edition (ISO 10079-1:1991), 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 — Safety requirements*

— *Part 2: Manually powered suction equipment*

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

Annexes A to L of this part of ISO 10079 refer to Appendixes A to L of IEC 60601:1988, respectively. Annexes M, N and O are for information only.