SLOVENSKI STANDARD
SIST EN ISO 10079-3:2009

01-junij-2009

Nadomeġļ a:
SIST EN ISO 10079-3:2000

Medicinska sukcijska (aspiracijska) oprema - 3. del: Podtlaļ na ali tlaļ na sukcijska (aspiracijska) oprema (ISO 10079-3:1999)

Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999)

Medizinische Absauggeräte - Teil 3: Vakuum- oder druckquellenbetriebene Absauggeräte (ISO 10079-3:1999)

Appareils d'aspiration médicale - Partie 3: Appareils d'aspiration alimentés par une source de vide ou de pression (ISO 10079-3:1999)

Ta slovenski standard je istoveten z: **EN ISO 10079-3:2009**

ICS:

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

SIST EN ISO 10079-3:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-3

March 2009

ICS 11.040.10

Supersedes EN ISO 10079-3:1999

English Version

Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999)

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Medizinische Absauggeräte - Teil 3: Vakuum- oder druckquellenbetriebene Absauggeräte (ISO 10079-3:1999)

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

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Foreword

The text of ISO 10079-3:1999 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 10079-3:2009 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 10079-3:1999.

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 10079-3:1999 has been approved by CEN as a EN ISO 10079-3:2009 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	
4.1, 4.2, 4.3, 4.4	4, 8.1	
-	6a	This relevant Essential Requirement is not addressed in this European Standard
5, 6	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
5	1, 2, 3	
5.1.1	9.1	
5.1.2	9.2	
5.1.3	9.2, 10.1, 10.2	
5.1.4	9.2, 9.3	
5.1.5	9.1	
6	1, 2, 3, 9.2	
6.1	7.2, 7.5, 8.1	
6.2	7.2	
6.3	4, 7.6, 9.2	
6.4	9.1	

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
6.5	2	
6.5.1	12.8.2	
6.5.2	8.1	
6.5.3	7.2, 7.5, 12.8.2	
6.5.4	12.6, 12.8.2, 13.2	
6.6	10.1	
6.6.1 bis 6.6.8	12.9	
6.7	4	
6.8	4, 7.6, 9.2, 12.7.1	
6.9	4, 9.2	
6.10	4, 7.2, 7.5, 9.2, 12.7.1	
6.11	12.7.3	
7	3	
7.1, 7.2	9.2, 12.7.1	
8	3	
9.1, 9.2	9.1, 12.7.4	
10	10.1, 12.8.1	
11.1	4, 9.2	
11.2	5, 9.2	
12	9.1, 13.1	
12	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
12.1	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
12.1	13.3 (f)	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
13	9.1, 13, 13.1	
13	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
13	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
13	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard: covered by EN ISO 13485: 2003, subclause 4.2.3

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
-	1.2.2	This relevant EHSR is not addressed in this European Standard
-	1.5.4	This relevant EHSR is not fully addressed in this European Standard
-	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 10079-3

Second edition
1999-08-15

Medical suction equipment —

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

Appareils d'aspiration médicale —

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

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