Meditsiiniline vaakumaparatuur. Osa 3: Vaakum- või surveajamiga töötav vaakumaparatuur

Medical suction equipment - Part 3: Suction equipment powered from vacuum or pressure source

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10079-3:2009 sisaldab Euroopa standardi EN ISO 10079-3:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10079-3:2009 consists of the English text of the European standard EN ISO 10079-3:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 04.03.2009.	Date of Availability of the European standard text 04.03.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

Võtmesõnad: jõudluse hindamine, meditsiiniaparatuur, märgistus, ohutusnõuded, suruõhu abil töötavad seadmed, tehnilised andmed

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 10079-3

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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)

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

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 10079-3:2009: E

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.

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Medical suction equipment —

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

1 Scope

This part of ISO 10079 specifies safety and performance requirements for medical suction equipment powered from a vacuum or pressure source (see Figure 1). In particular it applies to connections for pipelines and Venturi attachments.

Suction equipment with components controlled by electrical means, e.g. electronic timing, may also need to comply with IEC 60601-1.

This part of ISO 10079 does not apply to electrically powered suction equipment, whether mains electricity or battery-powered, which is dealt with in ISO 10079-1, nor to manually powered suction equipment which is dealt with in ISO 10079-2, nor to the following:

a) central power supply (by vacuum/compressed air generation), piping systems of vehicles and buildings, and wall connectors;

b) catheter tubes, drains, curettes and suction tips;

c) syringes;

d) dental suction equipment;

e) waste gas scavenging systems;

f) laboratory suction;

g) autotransfusion systems;

h) passive urinary drainage;

i) closed systems for wound drainage;

j) gravity gastric drainage;

k) orally operated mucous extractors;

l) suction equipment where the collection container is downstream of the vacuum pump;

m) equipment marked as suction unit for permanent tracheostomy;

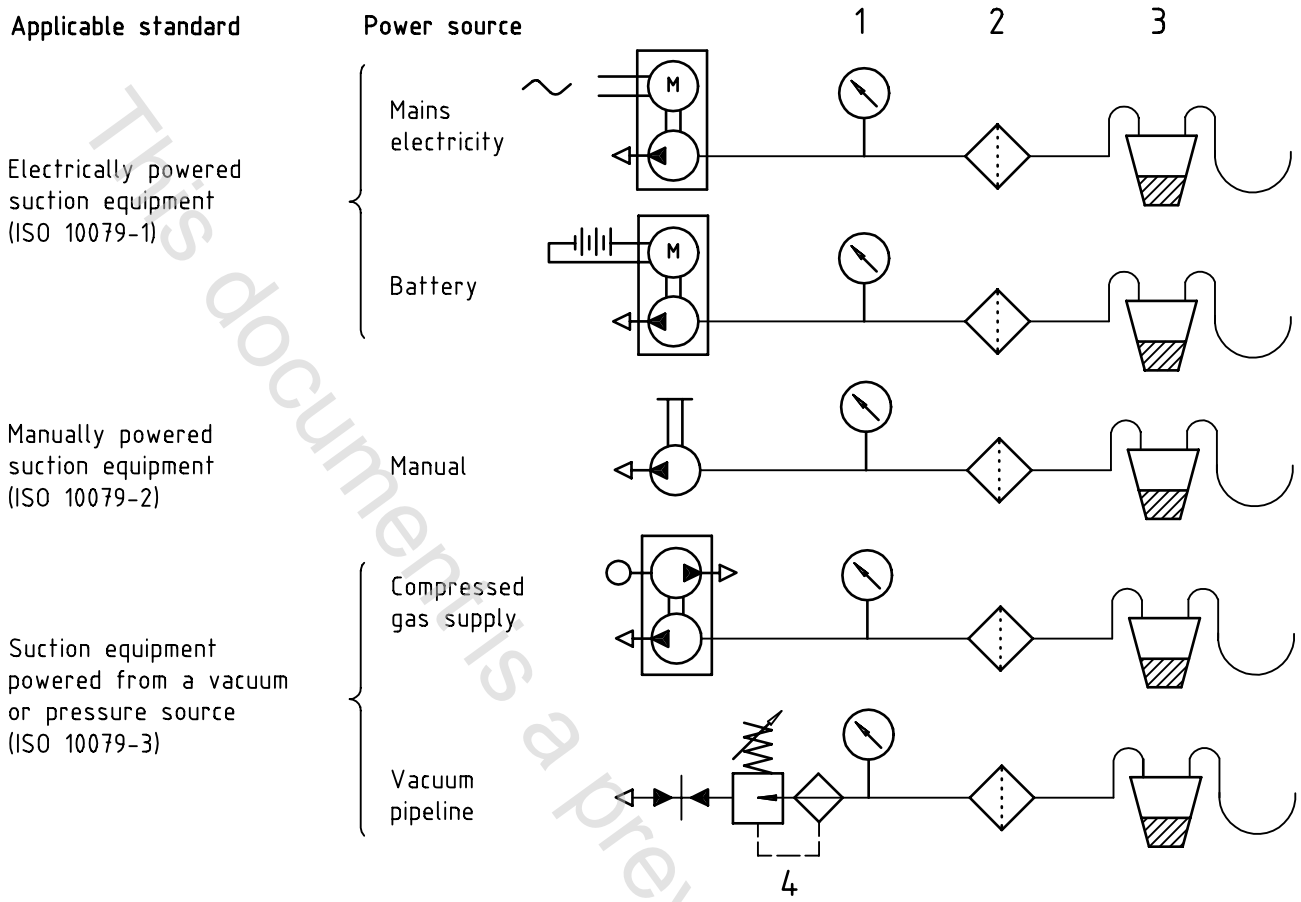
n) ventouse (obstetric) equipment;

o) neonatal mucous extractors;

p) breast pumps;

q) liposuction;

r) uterine aspiration.



Key

1 Vacuum indicator
2 Filter
3 Collection container
4 Vacuum regulator

NOTE 1 ISO 10079-1 applies to mains electricity and battery-powered suction equipment. ISO 10079-2 applies to manually powered suction equipment. ISO 10079-3 applies to suction equipment powered from a vacuum or pressure source.

NOTE 2 Components illustrated are not necessarily required by this part of ISO 10079.

NOTE 3 Suction equipment shown is an example only, and actual systems may consist of other arrangements and components not illustrated.

Figure 1 — Schematic drawing of suction equipment

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 10079. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10079 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for free-field conditions over a reflecting plane*.

ISO 5356-1:1996, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems*.

ISO 8836:1997, *Suction catheters for use in the respiratory tract*.

ISO 10079-1:1999, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements*.

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*; Amd. 1:1991 and Amd. 2:1995.

IEC 60651:1979, *Sound pressure meters*.