

SVENSK STANDARD

SS-EN ISO 10079-1:2015

Fastställt/Approved: 2015-12-01
Publicerad/Published: 2016-01-08
Utgåva/Edition: 4
Språk/Language: engelska/English
ICS: 11.040.10

Medicinsk sugutrustning – Del 1: Elektriskt driven sugutrustning (ISO 10079-1:2015)

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

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Europastandarden EN ISO 10079-1:2015 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 10079-1:2015.

Denna standard ersätter SS-EN ISO 10079-1:2009, utgåva 3.

The European Standard EN ISO 10079-1:2015 has the status of a Swedish Standard. This document contains the official English version of EN ISO 10079-1:2015.

This standard supersedes the Swedish Standard SS-EN ISO 10079-1:2009, edition 3.

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Denna standard är framtagen av kommittén för Anestesi- och respiratorutrustning, SIS/TK 329.

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EUROPEAN STANDARD

EN ISO 10079-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2015

ICS 11.040.10

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.

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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of an identical text or by endorsement, at the latest by May 2016, and conflicting national standards shall be withdrawn at the latest by November 2018.

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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.

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Endorsement notice

The text of ISO 10079-1:2015 has been approved by CEN as EN ISO 10079-1:2015 without any modification.

Medical suction equipment —

Part 1:

Electrically powered suction equipment

1 Scope

This part of ISO 10079 specifies safety and performance requirements for electrically powered medical and surgical suction equipment. It applies to equipment used in health care facilities such as hospitals, for domiciliary care of patients and for field and transport use.

This part of ISO 10079 does not apply to the following:

- a) central power supply (by vacuum/compressed air generation), piping systems of vehicles and buildings, and wall connectors;
- b) end-pieces such as suction catheters, drains, curettes, Yankauer suckers and suction tips;
- c) syringes;
- d) dental suction equipment;
- e) anaesthetic gas scavenging systems;
- f) laboratory suction;
- g) autotransfusion systems;
- h) mucus extractors including neonatal mucus extractors;
- i) suction equipment where the collection container is downstream of the vacuum pump;
- j) ventouse (obstetric) equipment;
- k) suction equipment marked for endoscopic use only;
- l) plume evacuation systems.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3744, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

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

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*¹⁾

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

1) The graphical symbol collections of ISO 7000, ISO 7001, and ISO 7010 are also available on the Online Browsing Platform <http://www.iso.org/obp>.