

# SVENSK STANDARD

## SS-EN ISO 10079-2:2014

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### **Medicinsk sugutrustning – Del 2: Manuellt driven sugutrustning (ISO 10079-2:2014)**

### **Medical suction equipment – Part 2: Manually powered suction equipment (ISO 10079-2:2014)**

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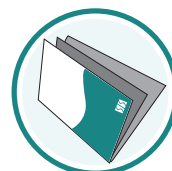
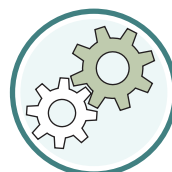
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Europastandarden EN ISO 10079-2:2014 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 10079-2:2014.

Denna standard ersätter SS-EN ISO 10079-2:2009, utgåva 3.

The European Standard EN ISO 10079-2:2014 has the status of a Swedish Standard. This document contains the official version of EN ISO 10079-2:2014.

This standard supersedes the Swedish Standard SS-EN ISO 10079-2:2009, edition 3.

**Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 10079-2:2014/  
Relations to other parts under the same general title - Extract from the Foreword of  
ISO 10079-2:2014**

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*

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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 10079-2**

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2014

ICS 11.040.10

Supersedes EN ISO 10079-2:2009

English Version

## Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:2014)

Appareils d'aspiration médicale - Partie 2: Appareils d'aspiration manuelle (ISO 10079-2:2014)

Medizinische Absauggeräte - Teil 2: Handbetriebene Absauggeräte (ISO 10079-2:2014)

This European Standard was approved by CEN on 15 February 2014.

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**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## Foreword

This document (EN ISO 10079-2:2014) 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 10079-2:2009.

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.

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### Endorsement notice

The text of ISO 10079-2:2014 has been approved by CEN as EN ISO 10079-2:2014 without any modification.





# Medical suction equipment —

## Part 2: Manually powered suction equipment

### 1 Scope

This part of ISO 10079 specifies safety and performance requirements for manually powered suction equipment intended for oro-pharyngeal suction. It applies to equipment operated by foot or by hand or both. [Annex D](#) illustrates the three parts of ISO 10079 by providing a schematic for typical systems.

The commonest use of manually powered suction is in situations outside of health care settings often described as field use or transport use. Use in these situations may involve extreme conditions of weather or terrain. Additional requirements for suction equipment intended for field and/or transport use are included in this part of ISO 10079.

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

- a) end pieces such as suction catheters, Yankauer sucker and suction tips;
- b) dental suction equipment;
- c) mucus extractors, including neonatal mucus extractors.

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

ISO 7000<sup>1)</sup>, *Graphical symbols for use on equipment — Registered symbols*

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

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

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 80369 (all parts), *Small-bore connectors for liquids and gases in healthcare applications*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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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>.

**3.1  
collection container**

container in which liquids and solid particles are collected

**3.2  
end-piece**

that part of the suction equipment applied to the patient which begins at the site where material is drawn in and ends at the first detachable connection

Note 1 to entry: Examples of commonly used end-pieces are a Yankauer sucker and a suction catheter.

**3.3  
exhaust port**

opening through which exhaust gas is discharged

**3.4  
field use**

use of suction equipment in situations outside of the health care facility at the site of accidents or other emergencies

**3.5  
filter**

device for retention of particulate matter

**3.6  
free air flowrate**

rate of unrestricted flow of air through a designated inlet

**3.7  
inlet port**

opening through which liquid, solid particles or gas enter

**3.8  
intermediate tubing**

tubing between the collection container and the vacuum source

**3.9  
manually powered suction**

generation of vacuum by direct human effort

**3.10  
overflow protection device**

device intended to prevent liquid or solid particles from entering the intermediate tubing

**3.11  
single fault condition**

condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

Note 1 to entry: Maintenance of equipment is considered a normal condition.

**3.12  
suction**

application of vacuum to remove liquid, solid particles or gas

**3.13  
suction tubing**

tubing for conduction of liquid, solid particles or gas between the end-piece and the collection container

**3.14  
transport use**

use during patient transport outside of a health care facility (e.g. in an ambulance or aeroplane)

### 3.15

#### **vacuum level**

pressure less than atmospheric pressure

Note 1 to entry: In this part of ISO 10079, vacuum level is expressed as a difference from atmospheric pressure.

### 3.16

#### **vacuum level indicator**

device for displaying the vacuum level

### 3.17

#### **vacuum source**

component of device for generating vacuum

## 4 General requirements

### 4.1 Risk management

**4.1.1** This part of ISO 10079 specifies requirements that are generally applicable to risks associated with manually powered suction equipment. An established risk management process shall be applied to the design of the device. The risk management process shall include the following elements:

- risk analysis;
- risk evaluation;
- risk control;
- production and post-production information.

EXAMPLE ISO 14971.

Check compliance by inspection of the risk management file.

**4.1.2** Manually powered suction equipment shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using risk management procedures in accordance with ISO 14971 and which are associated with their intended application, in normal and in single fault condition.

NOTE A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations might remain undetected over a period of time and, as a consequence, might lead to an unacceptable risk. In that case, a subsequent detected fault condition needs to be considered as a single fault condition. Specific risk control measures need to be determined within the risk management process to deal with such situations.

Check compliance by inspection of the risk management file.

**4.1.3** Where requirements of this part of ISO 10079 refer to freedom from unacceptable risk, the acceptability or unacceptability of this risk shall be determined by the manufacturer in accordance with their policy for determining acceptable risk.

Check compliance by inspection of the risk management file.

**4.1.4** The manufacturer may use type tests different from those detailed within this part of ISO 10079, if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in [Annex A](#) of this part of ISO 10079.

Check compliance by inspection of the technical file.