SLOVENSKI STANDARD
SIST EN ISO 10079-4:2021

01-december-2021

Medicinska sukcijska (aspiracijska) oprema - 4. del: Splošne zahteve (ISO 10079-4:2021)

Medical suction equipment - Part 4: General requirements (ISO 10079-4:2021)

Medizinische Absauggeräte - Teil 4: Allgemeine Anforderungen (ISO 10079-4:2021)

Appareils d'aspiration médicale - Partie 4: Exigences générales (ISO 10079-4:2021)

Ta slovenski standard je istoveten z: **EN ISO 10079-4:2021**

ICS:

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

SIST EN ISO 10079-4:2021 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10079-4

October 2021

ICS 11.040.10

English Version

Medical suction equipment - Part 4: General requirements (ISO 10079-4:2021)

Appareils d'aspiration médicale - Partie 4: Exigences générales (ISO 10079-4:2021)

Medizinische Absauggeräte - Teil 4: Allgemeine Anforderungen (ISO 10079-4:2021)

This European Standard was approved by CEN on 26 July 2021.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

European foreword

This document (EN ISO 10079-4:2021) 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 April 2022, and conflicting national standards shall be withdrawn at the latest by April 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10079-4:2021 has been approved by CEN as EN ISO 10079-4:2021 without any modification.

INTERNATIONAL STANDARD

ISO 10079-4

First edition
2021-08

Medical suction equipment —

Part 4: General requirements

Appareils d'aspiration médicale —

Partie 4: Exigences générales

Reference number
ISO 10079-4:2021(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment* subcommittee SC 8, *Suction devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 10079 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Previously the ISO 10079 series of medical *suction* equipment standards comprised parts ISO 10079-1,[2] ISO 10079-2 [3] and ISO 10079-3 [4] which had many common requirements. It was thought that combining these common requirements into this new part 4 would prevent the inconsistencies that had resulted from developing three different parts with common requirements and would make any future revision/amendment easier to manage.

This document contains those requirements that are common to electrically, manually and gas-powered medical *suction* equipment.

Medical suction equipment —

Part 4: General requirements

1 Scope

This document specifies general requirements for medical *suction* equipment that are common to all parts of the ISO 10079 series.

This document is not applicable to the following:

a) *end-pieces* such as *suction* catheters, drains, curettes, Yankauer suckers and *suction* tips;

b) syringes;

c) dental *suction* equipment;

d) anaesthetic gas scavenging systems;

e) laboratory *suction*;

f) autotransfusion systems;

g) mucus extractors including neonatal mucus extractors;

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

i) ventouse (obstetric) equipment;

j) *suction* equipment marked for endoscopic use only; and

k) plume evacuation systems.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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 20417, *Medical devices — Information to be provided by the manufacturer*