

SLOVENSKI STANDARD

SIST EN ISO 19054:2006/A1:2017

01-februar-2017

Tračni nosilci za pritrditev medicinske opreme (ISO 19054:2005/Amd 1:2016)

Rail systems for supporting medical equipment (ISO 19054:2005/Amd 1:2016)

Schienensysteme zum Halten medizinischer Geräte (ISO 19054:2005/Amd 1:2016)

Systèmes de rails de support pour appareils médicaux (ISO 19054:2005/Amd 1:2016)

Ta slovenski standard je istoveten z: EN ISO 19054:2006/A1:2016

[SIST EN ISO 19054:2006/A1:2017](https://standards.iteh.ai/catalog/standards/sist/752e4c13-5ce1-46ac-92c1-428c034ee996/sist-en-iso-19054-2006-a1-2017)

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ICS:

11.040.99 Druga medicinska oprema Other medical equipment

SIST EN ISO 19054:2006/A1:2017 **en**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 19054:2006/A1

December 2016

ICS 11.040.99

English Version

**Rail systems for supporting medical equipment (ISO
19054:2005/Amd 1:2016)**

Systèmes de rails de support pour appareils médicaux
(ISO 19054:2005/Amd 1:2016)

Schienensysteme zum Halten medizinischer Geräte
(ISO 19054:2005/Amd 1:2016)

This amendment A1 modifies the European Standard EN ISO 19054:2006; it was approved by CEN on 30 November 2016.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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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 19054:2006/A1:2016) 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 Amendment to the European Standard EN ISO 19054:2006 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2017, and conflicting national standards shall be withdrawn at the latest by June 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 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.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 19054:2005/Amd1:2016 has been approved by CEN as EN ISO 19054:2006/A1:2016 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] / [M/295 concerning the development of European Standards related to medical devices] / [reference number and title of any other standardization request as relevant] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 160].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

**Table ZA.1 — Correspondence between this European Standard and Annex I of Directive
93/42/EEC [OJ L 169]**

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.1	5.2.6	Partly covered

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

**ISO
19054**

First edition
2005-07-01

AMENDMENT 1
2016-11-15

Rail systems for supporting medical equipment

AMENDMENT 1

Systèmes de rails de support pour appareils médicaux

AMENDEMENT 1

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

Amendment 1 to ISO 19054:2005 was prepared by ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

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