Meditsiiniaparatuuri paralleelsüsteemid

Rail systems for supporting medical equipment

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 19054:2006 sisaldab Euroopa standardi EN ISO 19054:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 31.07.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 19054:2006 consists of the English text of the European standard EN ISO 19054:2006. This document is endorsed on 31.07.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standard esitab põhinõuded, mis tagavad käesoleva standardi alla kuuluvate paralleelsüsteemide ja meditsiiniaparatuuri omavahelise ühtesobivuse, et võimaldada meditsiiniaparatuuri vahetatavus ühelt paralleelsüsteemilt teisele.	**Scope:** This International Standard specifies basic requirements to ensure compatibility between rail systems complying with this International Standard and medical equipment in order to facilitate the transfer of medical equipment from one rail system to another.

ICS 11.040.99

Võtmesõnad: kaitserelsid, kinnitused, meditsiiniaparatuur, mehaanilised omadused, mõõtmed, märgistus, määratlused, pakkimine, sertifitseerimine, teave, testimine, vahetatavus, vastavus tehnilistele tingimustele

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 19054

June 2006

ICS 11.040.99

Supersedes EN 12218:1998

English Version

Rail systems for supporting medical equipment (ISO 19054:2005)

Systèmes de rails de support pour appareils médicaux (ISO 19054:2005)

Schienensysteme zum Halten medizinischer Geräte (ISO 19054:2005)

This European Standard was approved by CEN on 9 June 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, 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

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Foreword

The text of ISO 19054:2005 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 19054:2006 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 December 2006, and conflicting national standards shall be withdrawn at the latest by June 2008.

This document supersedes EN 12218:1998.

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, 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.

Endorsement notice

The text of ISO 19054:2005 has been approved by CEN as EN ISO 19054:2006 without any modifications.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical devices

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 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 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 — Correspondence between this European Standard and Directive 93/42/EEC Medical devices

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8.1	13.6 c), 13.6 d)	
8.2	13.1, 13.6 c), 13.6 d)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 19054

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Rail systems for supporting medical equipment

Systèmes de rails de support pour équipement médical

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 19054 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

Introduction

This International Standard specifies basic requirements and dimensions for rail systems used for supporting medical equipment. A rail system consists of a number of components that can be assembled into different configurations.

Rail systems allow medical equipment such as flowmeters, suction devices and luminaires to be placed near the patient. They can be mounted in many different locations in health care facilities and in ambulances and other means of transportation and on many different pieces of equipment such as medical supply units, ceiling pendants, trolleys, beds, ventilators and anaesthetic workstations.

Medical equipment can be attached to a rail by rail clamps directly or using other components of dimensions which are specified in this International Standard. Rail clamps are required to be compatible with rails which have dimensions specified in this International Standard.

Rail systems have to be fitted to different kinds of load-bearing structures which can vary from solid concrete walls or thin plasterboard partitions to the covers of medical equipment. This can create hazards to the equipment and to the patient. Patients with accompanying medical equipment are frequently moved either to or within health care facilities. Lack of standardization of rail systems in different locations can create hazardous situations in the transfer of the patient from one location to another.

Annex B contains rationale statements for some of the requirements of this International Standard. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex B. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revisions.

Rail systems for supporting medical equipment

1 Scope

This International Standard specifies basic requirements to ensure compatibility between rail systems complying with this International Standard and medical equipment in order to facilitate the transfer of medical equipment from one rail system to another. The specifications for rail systems include dimensions, strength and information to be supplied by the manufacturer.

This International Standard applies only to rail systems intended to be mounted horizontally.

This International Standard does not specify either the structures to which a rail system can be attached or the types of medical equipment that can be supported.

This International Standard does not apply to overhead rail systems for supporting curtains and infusion devices.

NOTE 1 Some medical equipment can be attached to the rail by means that are outside the scope of this International Standard.

NOTE 2 It is expected that particular standards will be prepared to cover applications for which the rail systems specified in this International Standard are unsuitable.

2 Normative references

The following referenced documents are indispensable for the application 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 1302:2002, *Geometrical Product Specifications (GPS) — Indication of surface texture in technical product documentation*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 6506-1:1999, *Metallic materials — Brinell hardness test — Part 1: Test method*

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

EN 980, *Graphical symbols for use in the labelling of medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 and the following apply.

3.1
commissioning
proof of function to verify that the agreed system specification is met and is accepted by the user or the representative of the user