



SLOVENSKI STANDARD

SIST EN ISO 19054:2006

01-september-2006

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SIST EN 12218:2000
SIST EN 12218:2000/A1:2002

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

Schienensysteme zum Halten medizinischer Geräte (ISO 19054:2005)

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

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Ta slovenski standard je istoveten z: EN ISO 19054:2006

ICS:

11.040.99 Druga medicinska oprema Other medical equipment

SIST EN ISO 19054:2006

en

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Contents

Page

| | |
|---|----------|
| Foreword | 3 |
| Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical devices..... | 4 |

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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.

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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

| Clause(s)/sub-clause(s) of this EN | Essential Requirements (ERs) of Directive 93/42/EEC | Qualifying remarks/Notes |
|------------------------------------|---|--------------------------|
| 4.1 | 1 | |
| 4.2 | 2 | |
| 4.3 | 2 | |
| 4.3.1 | 4, 7.1 | |
| 4.3.2 | 4, 7.1 | |
| 4.4 | 9.2, 12.6 | |
| 5.1.1 | 9.1 | |
| 5.1.2 | 9.1 | |
| 5.1.3 | 9.1 | |
| 5.2.2 | 9.1 | |
| 5.2.7 | 3, 12.7.1 | |
| 5.2.7.1 | 12.7.1 | |
| 5.2.7.2 | 12.7.1 | |
| 5.2.7.3 | 3, 12.7.1 | |
| 5.2.8 | 3, 12.7.1 | |
| 5.3 | 3, 9.1, 12.7.1 | |
| 5.4 | 3, 9.1, 12.7.1 | |
| 5.4.3 | 9.1 | |
| 5.4.7 | 3, 12.7.1 | |
| 5.4.8 | 12.7.1 | |
| 5.5.1 | 9.1 | |

| | | |
|--------|------------------------|--|
| 5.5.2 | 3, 9.1, 12.7.1 | |
| 5.6.1 | 9.1 | |
| 5.6.2 | 12.7.1 | |
| 5.7.1 | 9.1 | |
| 5.7.2 | 3, 9.1, 12.7.1 | |
| 5.8.1 | 9.1 | |
| 5.8.2 | 12.7.1 | |
| 5.9 | 3, 12.7.1 | |
| 6.1 | 13.1 | |
| 6.1 a) | 13.4 | |
| 6.1 b) | 13.3 a), 13.6 a) | |
| 6.1.c) | 13.3 b), 13.6 a) | |
| 6.1 d) | 13.3 d), 13.5 | |
| 6.1 e) | 13.3 m) | |
| 6.2 a) | 13.1 | |
| 6.2 b) | 13.3 k) | |
| 7.1.2 | 3, 12.7.1 | |
| 7.1.4 | 13.1 | |
| 7.1.5 | 13.1 | |
| 7.2 | 2, 3, 13.6 d) | |
| 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.

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INTERNATIONAL STANDARD

ISO
19054

First edition
2005-07-01

Rail systems for supporting medical equipment

Systèmes de rails de support pour équipement médical

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Contents

Page

| | |
|---|----|
| Foreword..... | iv |
| Introduction | v |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms and definitions..... | 1 |
| 4 General Requirements..... | 4 |
| 4.1 Safety | 4 |
| 4.2 * Alternative construction | 4 |
| 4.3 Materials | 4 |
| 4.4 Electrical requirements | 4 |
| 5 Rail system requirements | 4 |
| 5.1 Rail supports | 4 |
| 5.2 Rail..... | 4 |
| 5.3 Joining of rails | 9 |
| 5.4 Rail clamp | 9 |
| 5.5 Equipment mount holder | 11 |
| 5.6 Equipment mount | 12 |
| 5.7 Equipment mount pin holder | 13 |
| 5.8 Equipment mount pin | 14 |
| 5.9 * Mechanical characteristics of the rail after installation | 14 |
| 6 Marking, labelling and packaging | 15 |
| 7 Testing, commissioning and certification..... | 16 |
| 7.1 Tests after installation..... | 16 |
| 7.2 Certification of the installed rail system..... | 16 |
| 8 Information to be supplied by the manufacturer..... | 16 |
| 8.1 Upon delivery of rail and supports | 16 |
| 8.2 Upon delivery of other components of the rail system | 17 |
| Annex A (informative) Example of a form for certification of the rail system..... | 18 |
| Annex B (informative) Rationale | 19 |
| Annex C (informative) Special national and regional conditions for electrical installations | 20 |
| Bibliography | 21 |

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*.

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