

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

ICS 11.040.99

## National foreword

This British Standard is the UK implementation of EN ISO 19054:2006+A1:2016. It is identical to ISO 19054:2005, incorporating amendment 1:2016. It supersedes BS EN ISO 19054:2006 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

**Compliance with a British Standard cannot confer immunity from legal obligations.**

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|                 |                                                                                       |
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|                 |                                                                                       |

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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## **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.

## **Foreword to amendment A1**

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.**

## Contents

Page

|                                                                                                   |     |
|---------------------------------------------------------------------------------------------------|-----|
| Foreword.....                                                                                     | vi  |
| Introduction .....                                                                                | vii |
| 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*.

## 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.

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