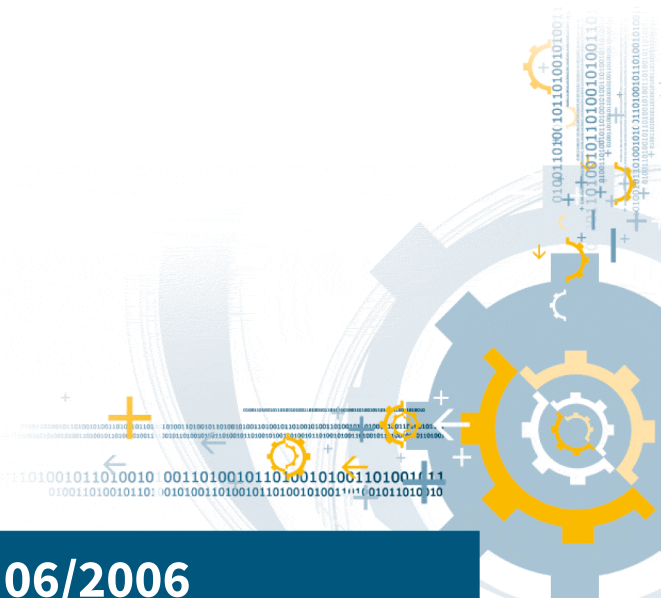




Institut luxembourgeois de la normalisation  
de l'accréditation, de la sécurité et qualité  
des produits et services

## ILNAS-EN ISO 19054:2006



## National Foreword

This European Standard EN ISO 19054:2006 was adopted as Luxembourgish Standard ILNAS-EN ISO 19054:2006.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

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EUROPEAN STANDARD <sup>ILNAS-EN ISO 19054:2006</sup> **EN ISO 19054**  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

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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## 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**

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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## **Rail systems for supporting medical equipment**

*Systèmes de rails de support pour équipement médical*