SLOVENSKI STANDARD
SIST EN ISO 9919:2009

01-maj-2009

Nadomeġļa:
SIST EN ISO 9919:2005

Elektromedicinska oprema - Posebne zahteve za osnovno varnost in bistvene lastnosti pulznega oksimetra za uporabo v medicini (ISO 9919:2005)

Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)

Medizinische elektrische Geräte Besondere Festlegungen für die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale von Pulsoximetriegeräten für den medizinischen Gebrauch (ISO 9919:2005)

Appareils électromédicaux - Règles particulières de sécurité et performances essentielles du matériel utilisé pour les oxymètres de pouls à usage médical (ISO 9919:2005)

Ta slovenski standard je istoveten z: **EN ISO 9919:2009**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 9919:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9919

April 2009

ICS 11.040.10

Supersedes EN ISO 9919:2005

English Version

Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)

Appareils électromédicaux - Règles particulières de sécurité et performances essentielles du matériel utilisé pour les oxymètres de pouls à usage médical (ISO 9919:2005)

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This European Standard was approved by CEN on 14 March 2009.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 9919:2005 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 9919:2009 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 October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 supersedes EN ISO 9919:2005.

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 EC Directive.

For relationship with EC Directive, 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, 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 the United Kingdom.

Endorsement notice

The text of ISO 9919:2005 has been approved by CEN as a EN ISO 9919:2009 without any modification.

Annex ZA
(informative)

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

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 on 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.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.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
4.101, 4.102	3, 6	
4.103	6, 9.1	
6.1	2,9.1, 13.1	
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
6.1 d)	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.6 (h)(3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
6.8.2 aa) 21	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard: covered by EN ISO 13485: 2003, subclause 4.2.3

Table ZA.1 (continued)

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
6.1 d) 1st dash	13.1	
6.1 d) 4th dash	12.4	
6.1 f)	9.1, 13.1	
6.1 aa)	10.3	
6.1 bb)	13.3 f), 13.6 h)	
6.1 cc)	13.3 c), 13.3 m)	
6.1 dd)	13.3 e)	
6.8.2	6, 13.6	
6.8.2 aa) 1)	13.6 b)	
6.8.2 aa) 2)	11.4.1, 13.6 j)	
6.8.2 aa) 3)	13.6 b), 13.6 f), 13.6 k), 13.6 l)	
6.8.2 aa) 4)	13.6 b), 13.6 p)	
6.8.2 aa) 5)	13.6 b)	
6.8.2 aa) 7)	13.6 d)	
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6.8.2 aa) 13), 6.8.2 aa) 14), 6.8.2 aa) 15), 6.8.2 aa) 16), 6.8.2 aa) 17),	13.6 b)	
6.8.2 aa) 19)	13.6 g)	
6.8.2 aa) 20)	13.6 c), 13.6 d)	
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6.8.3 aa) 1), 6.8.3 aa) 2)	13.6 d)	
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44.6	7.6	
44.7	8.1, 8.4, 8.6	
46	10.2	
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Table ZA.1 (continued)

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
48	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
49	4, 12.2, 12.3	
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WARNING - Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 9919

Second edition
2005-03-15

Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

Appareils électromédicaux — Règles particulières de sécurité et performances essentielles du matériel utilisé pour les oxymètres de pouls à usage médical

Reference number
ISO 9919:2005(E)

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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 9919 (IEC 60601-2-54) was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition cancels and replaces the first edition (ISO 9919:1992), which has been technically revised.