SLOVENSKI STANDARD
SIST EN ISO 9360-2:2009

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Nadomeģ ļa:
SIST EN ISO 9360-2:2003

Anestezijska in dihalna oprema - Izmenjevalniki toplote in vlage (HMEs) za navlaģevanje dihalnih plinov v ļ loveku - 2. del: HMEs za uporabo pri pacientih s traheostomijo z najmanjģo dihalno prostornino 250 ml (ISO 9360-2:2001)

Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml (ISO 9360-2:2001)

Anästhesie- und Beatmungsgeräte - Wärme- und Feuchtigkeitsaustauscher zur Anfeuchtung von Atemgasen beim Menschen - Teil 2: Wärme- und Feuchtigkeitsaustauscher zur Verwendung bei tracheostomierten Patienten mit Mindesthubvolumina von 250 ml (ISO 9360-2:2001)

Matériel d'anesthésie et de réanimation respiratoire - Échangeurs de chaleur et d'humidité (ECH) utilisés pour humidifier les gaz respirés par les êtres humains - Partie 2: ECH pour utilisation avec des patients trachéotomisés ayant des volumes courants d'au moins 250 ml (ISO 9360-2:2001)

Ta slovenski standard je istoveten z: **EN ISO 9360-2:2009**

ICS:

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

SIST EN ISO 9360-2:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9360-2

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ICS 11.040.10

Supersedes EN ISO 9360-2:2002

English Version

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This European Standard was approved by CEN on 28 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

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Foreword

The text of ISO 9360-2:2001 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 9360-2:2009 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 9360-2:2002.

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 9360-2:2001 has been approved by CEN as a EN ISO 9360-2:2009 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 EU Directives

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	13.2	
5	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
5.1	9.1, 13.6 c)	
5.2	9.1, 13.6 c)	
5.3	8.3	
5, 7	1 (2nd paragraph, 1st dash)	This relevant Essential Requirement is not fully addressed in this European Standard
5,7	1 (2nd paragraph, 2nd dash)	This relevant Essential Requirement is not fully addressed in this European Standard
-	6a	This relevant Essential Requirement is not addressed in this European Standard
7.1 a)	9.1, 13.2, 13.3 k), 13.6 c)	
7.1 b)	9.1, 13.2, 13.3 j)	
7.2	13.1	
7.2	7.5 (2nd paragraph)	This relevant Essential Requirement is not addressed in this European Standard

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
7.2	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
7.2 a)	13.3 a)	
7.2 b)	13.3 b)	
7.2 c)	8.7, 13.3 c)	
7.2 d)	13.3 i)	
7.2 e)	13.3 l)	
7.2 f)	13.3 e)	
7.3	13.3 f)	
7.3	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
7.4	13.1	
7.4	7.5 (3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
7.4	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
7.4	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
7.4 a)	13.1, 13.6 a), 13.6 b)	
7.4 b)	9.1, 13.3 j)	
7.4 d)	13.6 b)	
7.4 f)	13.3 m), 13.6 h)	
7.4 g)	13.3 j), 13.3 k)	
7.4 k)	13.6 n)	

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

INTERNATIONAL STANDARD

ISO 9360-2

First edition
2001-04-15

Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans

Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml

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