SLOVENSKI STANDARD
SIST EN ISO 9360-1:2009

01-julij-2009

Nadomeģ ļa:
SIST EN ISO 9360-1:2000

Anestezijska in dihalna oprema - Izmenjevalniki toplote in vlage (HMEs) za navlaģevanje dihalnih plinov v ļ loveku - 1. del: HMEs za uporabo z najmanjģo dihalno prostornino 250 ml (ISO 9360-1:2000)

Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)

Anästhesie- und Beatmungsgeräte - Wärme- und Feuchtigkeitsaustauscher zur Anfeuchtung von Atemgasen beim Menschen - Teil 1: Wärme- und Feuchtigkeitsaustauscher zur Verwendung bei Mindesthubvolumina von 250 ml (ISO 9360-1:2000)

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 1: ECH pour utilisation avec des volumes courants d'au moins 250 ml (ISO 9360-1:2000)

Ta slovenski standard je istoveten z: **EN ISO 9360-1:2009**

ICS:

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

SIST EN ISO 9360-1:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9360-1

April 2009

ICS 11.040.10

Supersedes EN ISO 9360-1:2000

English Version

Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)

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 1: ECH pour utilisation avec des volumes courants d'au moins 250 ml (ISO 9360-1:2000)

Anästhesie- und Beatmungsgeräte - Wärme- und Feuchtigkeitsaustauscher zur Anfeuchtung von Atemgasen beim Menschen - Teil 1: Wärme- und Feuchtigkeitsaustauscher zur Verwendung bei Mindesthubvolumina von 250 ml (ISO 9360-1:2000)

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 9360-1:2000 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 9360-1:2009 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 9360-1:2000.

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 9360-1:2000 has been approved by CEN as a EN ISO 9360-1:2009 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
-	7.5 (2nd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
-	7.5 (3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
5.1	9.1, 13.6 c)	
5.2	9.1, 13.6 c)	
5.3	8.3	
5, 6, 7	1 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
5, 6, 7	1 (2nd paragraph, 1st dash)	This relevant Essential Requirement is not fully addressed in this European Standard
5, 6, 7	1 (2nd paragraph, 2nd dash)	This relevant Essential Requirement is not fully addressed in this European Standard

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
-	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	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.3 (f)	This relevant Essential Requirement is not addressed in this European Standard
-	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not 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)	
7.4	13.1	
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)	13.6 b)	
7.4 g)	13.6 b)	
7.4 h)	13.3 j), 13.3 k)	
7.4 i)	13.3 m), 13.6 h)	
7.4 j)	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 9360-1

First edition
2000-03-15

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

Part 1: HMEs for use with minimum tidal volumes of 250 ml

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 1: ECH pour utilisation avec des volumes courants d'au moins 250 ml

Reference number
ISO 9360-1:2000(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 3.

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 part of ISO 9360 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9360-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This first edition of ISO 9360-1 cancels and replaces, in part, the first edition of ISO 9360 (ISO 9360:1992), which has been technically revised.

ISO 9360 consists of the following parts, under the general title *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans*:

— *Part 1: HMEs for use with minimum tidal volumes of 250 ml*

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

Annexes A and B of this part of ISO 9360 are for information only.