



SLOVENSKI STANDARD SIST EN ISO 9360-2:2003

01-marec-2003

Anestezijska in dihalna oprema - Izmenjevalniki toplote in vlage (HMEs) za navlaževanje dihalnih plinov v l'loveku - 2. del: HMEs za uporabo pri pacientih z traheostomijo z najmanjšo dihalno prostornino 250 ml (ISO 9360-1:2001)

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)

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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 - Echangeurs 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 9360-2:2002

ICS:

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

EN ISO 9360-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2002

ICS 11.040.10

English version

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)

Matériel d'anesthésie et de réanimation respiratoire -
Echangeurs 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)

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)

This European Standard was approved by CEN on 23 September 2002.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 9360-2:2002 (E)

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 9360-2:2002 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 May 2003, and conflicting national standards shall be withdrawn at the latest by May 2003.

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 ZB, 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Endorsement notice

The text of ISO 9360-2:2001 has been approved by CEN as EN ISO 9360-2:2002 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

Annex ZA (normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 4135	2001	Anaesthetic and respiratory equipment – Vocabulary	EN ISO 4135	2001
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	EN ISO 9360-1	2000

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Annex ZB

(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives.

This European Standard 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 93/42/EEC.

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

The following clauses of this standard, as given in Table ZB.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZB.1 – Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding essential requirements of Directive 93/42/EEC	Comments
4	13.2	
5.1	9.1, 13.6 c)	
5.2	9.1, 13.6 c)	
5.3	8.3	
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 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 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)	

INTERNATIONAL
STANDARDISO
9360-2First 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**iTeh STANDARD PREVIEW
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*Matériel d'anesthésie et de réanimation respiratoire — Échangeurs de
chaleur et d'humidité (ECH) utilisés pour humidifier les gaz respirés par les
êtres humains*

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*Partie 2: ECH pour utilisation avec des patients trachéotomisés ayant des
volumes courants d'au moins 250 ml*

Reference number
ISO 9360-2:2001(E)

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Printed in Switzerland

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