SLOVENSKI STANDARD
SIST EN ISO 5360:2012

01-april-2012

Nadomešča:
SIST EN ISO 5360:2009

Anestezijski hlapilniki (vaporizatorji) - Sistemi za nalivanje posebnih hlapnih anestetikov (ISO 5360:2012)

Anaesthetic vaporizers - Agent-specific filling systems (ISO 5360:2012)

Évaporateurs d'anesthésie - Systèmes de remplissage spécifiques à l'agent (ISO 5360:2012)

Ta slovenski standard je istoveten z: EN ISO 5360:2012

ICS:

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

SIST EN ISO 5360:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5360

January 2012

ICS 11.040.10

Supersedes EN ISO 5360:2009

English Version

Anaesthetic vaporizers - Agent-specific filling systems (ISO 5360:2012)

Évaporateurs d'anesthésie - Systèmes de remplissage spécifiques à l'agent (ISO 5360:2012)

Anästhesiemittelverdampfer - Substanzspezifische Füllsysteme (ISO 5360:2012)

This European Standard was approved by CEN on 14 January 2012.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, 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, Turkey and United Kingdom.

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

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Foreword

This document (EN ISO 5360:2012) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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 July 2012, and conflicting national standards shall be withdrawn at the latest by January 2015.

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 5360:2009.

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.

For relationship with EU 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, Croatia, 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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 5360:2012 has been approved by CEN as a EN ISO 5360:2012 without any modification.

Annex ZA
(informative)
Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This 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.

Once this standard is cited in the Official Journal of the European Union 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 International Standard and EU Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
4, 5, 6, 7, 9, 10	7.5, first paragraph, first sentence	
14.3 f), 14.2.1 last paragraph	7.5, second paragraph	Only the presence of phthalates is addressed; Presumption of conformity to labelling requirement only provided if the symbol defined in EN 15896 is used
4, 5, 6, 7, 9 and 11	9.1	Clauses 4 to 7 of this standard specify the design of the filling system to ensure specificity for anaesthetic agent and avoid the anaesthetic agent escaping into environment. Standard specifies colour coding of the anaesthetic agents including their generic names for a safe connection to anaesthetic systems Information on restrictions on use is addressed in the clauses on labelling and instructions for use, see 14.1 c), 14.2.1 c), d), e), f), 14.2.2, 14.3 a) – d) and f).
14	13.1	
11	13.2	Standard specifies colour coding of the anaesthetic agents including their generic names.
14.1 a), 14.2.1 a)	13.3 a)	
11, 14.1 c), 14.2.1 b), 14.2.1 c)	13.3 b)	packaging is not addressed
14.1 b)	13.3 d)	Presumption of conformity to ER 13.3 d) only provided if the word “LOT” is used
14.2.1.d)	13.3 e)	
14.1 a), 14.2.1 a)	13.3 a)	

continued

Table ZA.1 (*continued*)

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
14.2.1 e)	13.3 f)	Consistency across the Community is not addressed
14.2.1 f)	13.3 i)	
14.1 c), 14.2.1 c), 14.2.2,	13.3 j)	
14.2.2), 14.3 b)	13.3 k)	
14.1 b)	13.5	
14.3 a), 14.3 b)	13.6 a)	
14.3 c), 14.3 d)	13.6 d)	
14.3 g	13.6 h)	
14.3 h)	13.6 q)	

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

INTERNATIONAL STANDARD

ISO 5360

Third edition
2012-01-15

Anaesthetic vaporizers — Agent-specific filling systems

Évaporateurs d'anesthésie — Systèmes de remplissage spécifiques à l'agent

Reference number
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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 5360 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This third edition cancels and replaces the second edition (ISO 5360:2006), of which it constitutes a minor revision. In particular, it

— indicates in the Scope that requirements of agent-specific filling systems for anaesthetic vaporizers (not merely the dimensions) are specified,

— transfers the recommendations on materials from the Scope to an informative annex,

— refers to substances which are carcinogenic, mutagenic or toxic to reproduction in Clause 9 (leakage),

— introduces new requirements on usability (Clause 12) and clinical evaluation (Clause 13), and

— amends the requirements on information provided by the manufacturer (renumbered Clause 14).

