ANESTEETIKUMIAURUSTID. TOIMEAINESPETSIIFILISED TÄITESÜSTEEMID

Anaesthetic vaporizers - Agent-specific filling systems (ISO 5360:2016)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 5360:2016 sisaldab Euroopa standardi EN ISO 5360:2016 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 5360:2016 consists of the English text of the European standard EN ISO 5360:2016.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 16.03.2016.	Date of Availability of the European standard is 16.03.2016.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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English Version

Anaesthetic vaporizers - Agent-specific filling systems (ISO 5360:2016)

Évaporateurs d'anesthésie - Systèmes de remplissage spécifiques à l'agent (ISO 5360:2016)

Anästhesiemittelverdampfer - Substanzspezifische Füllsysteme (ISO 5360:2016)

This European Standard was approved by CEN on 7 November 2015.

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, Former Yugoslav Republic of Macedonia, 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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 5360:2016) 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 September 2016, and conflicting national standards shall be withdrawn at the latest by March 2019.

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 5360:2012.

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 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, Former Yugoslav Republic of Macedonia, 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 5360:2016 has been approved by CEN as EN ISO 5360:2016 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 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.

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 European Standard and EU Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European 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)	

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.

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