Anesteesia- ja hingamisseadmed. Hingamisagregaadid ja ühendusliitmikud

Anaesthetic and respiratory equipment - Breathing sets and connectors (ISO 5367:2014)

EESTI STANDARDIKESKUS
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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 5367:2014 sisaldab Euroopa standardi EN ISO 5367:2014 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 5367:2014 consists of the English text of the European standard EN ISO 5367:2014.
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 22.10.2014.	Date of Availability of the European standard is 22.10.2014.
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 and respiratory equipment - Breathing sets and connectors (ISO 5367:2014)

Matériel d'anesthésie et de réanimation respiratoire - Systèmes respiratoires et raccords (ISO 5367:2014)

Anästhesie- und Beatmungsgeräte - Atemsets und Verbindungsstücke (ISO 5367:2014)

This European Standard was approved by CEN on 18 July 2014.

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.

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Foreword

This document (EN ISO 5367:2014) 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 April 2015, and conflicting national standards shall be withdrawn at the latest by October 2017.

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 12342:1998+A1:2009.

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(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 5367:2014 has been approved by CEN as EN ISO 5367:2014 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 one 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 normative 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.

NOTE When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this standard.

Table ZA 1 — Correspondence between this European Document and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
5.1 4.3	7.1 (2nd, and 3rd indents)	
5.1.1 7.1 7.2	7.2	5.1.1 mandates that these devices shall satisfy the biological safety testing indicated in ISO 10993-1 7.1 and 7.2 covers the integrity of the packaging only for devices supplied sterile
4.1.1 4.1.2 5.1	7.3 first part	4.1.1, 4.1.2, and 5.1 mandates a risk assessment be carried out which does not exclude risks associated with materials and the substances with which they may come into contact.
5.1.3, 8.3.m)	7.5	Partly addressed by 5.1.3 and 8.3.m) calls specifically for a warning if phthalates are incorporated
7.1, 7.2, 8.3.a)	8.1	Partly addressed. 7.1 and 8.3.a) mandate that sterile devices are clearly marked according to EN 556–1 mandates the requirements of ISO 11607-1 to ensure that the packaging is suitable to prevent contamination during transportation and use.
7.2	8.3	Partly addressed by 7.2 which mandates the requirements of ISO 11607-1 that the packaging is suitable to prevent contamination during transportation and use.
7.1	8.4	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
7.1	8.5	
8.3.a)	8.7	Partly covered. Marked sterile if appropriate
5.3 5.4 5.5 5.6 6	9.1	Generally covered by mandating construction and testing of the interface connectors, leakage, resistance, compliance, resistance to tube collapse and kinking.
5.2 5.3 5.4 5.5 5.6 8.3 c) 8.3 d), e), f), g), m) 8.4.1 8.4.2 8.4.3 8.4.5	9.2 (first three indents)	Partly covered to address only the risk of injury in connection with their physical features by specifying sizing and marking conventions for the ID/OD of the breathing tubes, and leakage, resistance, and compliance when performance tested in accordance with parameters associated with a declared patient category.
5.3.1 5.3.2 5.3.3 5.3.5 5.3.6	12.7.4	Partly addressed for conical gas connectors only.
8 8.1 8.2 8.3 8.4	13.1	
8.1	13.2	Generally covered. Symbols are mandated in 8.1 to conform to EN 1041, ISO 7000 or ISO 15223-1
8.2 a) 8.3 i)	13.3 a)	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
8.3 c) 8.3 d) 8.3 e) and f) 8.3 g) 8.3 h)	13.3 b)	Covered for patient category, length, resistance, total compliance and internal diameter.
8.3 a)	13.3 c)	
8.3 j)	13.3 d)	
8.3.k)	13.3 e)	
8.3.b)	13.3 f)	
8.4.2 8.4.3 8.4.4 8.4.5	13.3 j)	Partly addressed with requirements for instructions for typical components or processes.
8.3 l) 8.3 m)	13.3 k)	
8.3 a)	13.3 m)	Partly addressed. Method of sterilization is addressed only as a recommendation.
8.4.5	13.5	Partly addressed. Limited to detachable connectors, which are sized in accordance with ISO 5356-1 instructs users on coaxial integrity testing
8, 8.1, 8.2, 8.3, 8.4	13.6 , a), b), c)	
8.4.4 8.3 l)	13.6 h)	Partly addressed. Risks associated with the reuse of devices marked for single use are covered partly by the risk management file and use of the informative Annex F Hazard identification for risk assessment
8.4.5	13.6 i)	Partly addressed. Details for coaxial set user tests are mandated
8.4.6	13.6 q)	

NOTE Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance to the Medical Devices Directive 93/42/EEC. This means that risks have to be reduced ‘as far as possible’, ‘to a minimum’, ‘to the lowest possible level’, ‘minimized’ or ‘removed’, according to the wording of the corresponding essential requirement

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