VÄIKESE AVAGA ÜHENDUSLIITMIKUD VEDELIKELE JA GAASIDELE TERVISHOIU RAKENDUSTES. OSA 5: ÜHENDUSLIITMIKUD JÄSEMETE MANSETTIDE TÄITMISRAKENDUSTES

Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 80369-5:2016 sisaldab Euroopa standardi EN 80369-5:2016 ingliskeelset teksti.	This Estonian standard EVS-EN 80369-5:2016 consists of the English text of the European standard EN 80369-5:2016.
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 04.11.2016.	Date of Availability of the European standard is 04.11.2016.
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.

ICS 11.040.25

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80369-5

November 2016

ICS 11.040.20

English Version

Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications (IEC 80369-5:2016)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 5: Raccords destinés à des applications au gonflage de brassard (IEC 80369-5:2016)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 5: Verbindungsstücke für Anwendungen mit aufblasbaren Manschettensystemen für Gliedmaßen (IEC 80369-5:2016)

This European Standard was approved by CENELEC on 8 April 2016. CEN and CENELEC 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 and CENELEC 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 and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees 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 Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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

European foreword

The text of document 62D/1306/FDIS, future edition 1 of IEC 80369-5, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice", ISO/TC 210 "Quality management and corresponding general aspects for medical devices" and CEN/CENELEC TC 3/WG 2 "Smallbore connectors", was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 80369-5:2016.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2017-05-04
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2019-11-04

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 80369-5:2016 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

ISO 3040:2009	NOTE	Harmonized as EN ISO 3040:2012 [1)] (not modified).
ISO 81060-1:2007	NOTE	Harmonized as EN ISO 81060-1:2012 (not modified).
IEC 60601-1-11:2015	NOTE	Harmonized as EN 60601-1-11:2015 (not modified).
IEC 60601-1-12:2014	NOTE	Harmonized as EN 60601-1-12:2015 (not modified).
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified).
IEC 80601-2-30:2009	NOTE	Harmonized as EN 80601-2-30:2010 (not modified).
IEC 80601-2-30:2009/A1:2013	NOTE	Harmonized as EN 80601-2-30:2010/A1:2015 (not modified).
ISO 80369-20:2015	NOTE	Harmonized as EN ISO 80369-20:2015 (not modified).
ISO 80369-6:2016	NOTE	Harmonized as EN ISO 80369-6:2016 (not modified).
ISO 80369-2 [2)]	NOTE	Harmonized as EN ISO 80369-2 [2)] (not modified).
ISO 80369-3:2016	NOTE	Harmonized as EN ISO 80369-3:2016 (not modified).

[1)] Superseded by EN ISO 3040:2016 (ISO 3040:2016).

[2)] At draft stage.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Publication	Year	Title	EN/HD	Year
-	-	Respiratory therapy equipment - Part 2: Tubing and connectors	EN 13544-2 +A1	2002 2009
ISO 5356-1	2004	Anaesthetic and respiratory equipment - Conical connectors - Part-1: Cones and sockets	EN ISO 5356-1	2004 [3)]
ISO 5356-1	2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets	EN ISO 5356-1	2015
ISO 5356-2	2006	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors	EN ISO 5356-2	2007 [4)]
ISO 5356-2	2012	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors	EN ISO 5356-2	2012
ISO 8185	2007	Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems	EN ISO 8185	2009
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	2012
ISO 80369-1	2010	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	EN ISO 80369-1	2010
ASTM D638-14	-	Standard test method for tensile properties of plastics	-	-
ASTM D790-10	-	Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials	-	-

[3)] Superseded by EN ISO 5356-1:2015 (ISO 5356-1:2015).

[4)] Superseded by EN ISO 5356-2:2012 (ISO 5356-2:2012).

Annex ZZ
(informative)

Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/023[1] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZZ.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 1 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 with Directive 93/42/EEC as amended by 2007/47/EC. 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.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZZ is based on normative references according to Annex ZA of this document.

NOTE 4 When an Essential Requirement does not appear in Table ZZ.1, it means that it is not addressed by this European Standard.

Table ZZ.1 – Correspondence between this European standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
9.1	5, 6.2	ER 9.1 is met with respect to the connector dimensions and disconnection only.
12.7.4	6.3	ER 12.7.4 is met with respect to stress cracking only.

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

[1] Replace with 'M/023 concerning the development of European standards related to medical devices' or with 'M/295 concerning the development of European standards related to medical devices', or with the reference number and title of any other standardization request as relevant.

CONTENTS