MEDITSIINILISED INFUSIOONISEADMED. OSA 11: RÕHKINFUSIOONISEADME ÜHEKORDSE KASUTUSEGA INFUSIOONIFILTRID

Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment (ISO 8536-11:2015)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 8536-11:2015 sisaldab Euroopa standardi EN ISO 8536-11:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8536-11:2015 consists of the English text of the European standard EN ISO 8536-11:2015.
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 17.06.2015.	Date of Availability of the European standard is 17.06.2015.
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 11.040.20

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-11

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Supersedes EN ISO 8536-11:2004

English Version

Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment (ISO 8536-11:2015)

Matériel de perfusion à usage médical - Partie 11 : Filtres à perfusion non réutilisables avec un matériel de perfusion sous pression (ISO 8536-11:2015)

Infusionsgeräte zur medizinischen Verwendung - Teil 11: Infusionsfilter zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO 8536-11:2015)

This European Standard was approved by CEN on 16 April 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

Ref. No. EN ISO 8536-11:2015 E

European foreword

This document (EN ISO 8536-11:2015) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

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 December 2015, and conflicting national standards shall be withdrawn at the latest by December 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 8536-11:2004.

— The former Clause 3 on designation has been deleted;

— Clause 9 on labelling was amended by addition of information regarding the usage of the symbol

“XXX” according ISO 7000, symbol 2725;

— Clause 10 on disposal has been added;

— A.4 has been amended;

— The former A.5 specifying a test for leakage of adapters with female and/or male conical fittings has

been deleted;

— Normative references and Bibliography have been updated;

— document has been editorially revised.

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 8536-11:2015 has been approved by CEN as EN ISO 8536-11:2015 without any modification.

Table – Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	**Equivalent dated standard**	
	EN	**ISO**
ISO 594-2	–-	ISO 594-2:1998
ISO 7000	–-	ISO 7000:2014
ISO 8536-8	EN ISO 8536-8:2015	ISO 8536-8:2015
ISO 10993-4	EN ISO 10993-4:2009	ISO 10993-4:2002 plus Amd.1:2006
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012

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, Medical devices.

Once this standard is cited in the Official Journal of the European Communities 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 Directive 93/42/EEC on medical devices

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clause 3, Clause 4, 5.1, 5.2, 5.3, 5.4, 5.5	7.2	The part of ER 7.2 relating to packaging is not addressed. For packaging see Clause 8 of this standard.
Clause 4, Clause 7	7.3	ER covered by biological evaluation.
5.3, 5.4, A.3, A.4	7.5	Only the first sentence is covered. Presumption of conformity with the Essential Requirements relating to the biological evaluation can only be provided if the manufacturer chooses to apply the ISO 10993- series of standards.
5.2, 5.3	7.6	
5.2, 5.3, 5.4	8.1	The part of ER 8.1 relating to handling is not addressed. Manufacturing processes are not covered. Only sterility of products is covered.
	8.3	
7.1	8.4	Only the sterilisation method is covered.
5.2	8.5	
9.2, 9.3	8.7	
5.5, 9.2 g)	9.1	The second sentence of ER 9.1 is not addressed.
Clause 3, Clause 4	9.2	
5.3, A.3	12.7.1	Only tensile strength is addressed.

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clause 9	13.1	
9.2 d), e), f), g), 9.3 c), d)	13.2	
9.2, 9.3	13.3	The part of 13.3 a) relating to the authorized representative is not addressed. Presumption of conformity to the rest of 13.3 a) is only provided if the name and address of the manufacturer are given. 13.3 d) is only covered if the batch number is preceded by the word 'LOT'. 13.3 g), h) is not addressed in the standard.
9.2, 9.3	13.4	13.4 is addressed regarding to the label.
9.2, 9.3	13.5	13.5 is not addressed regarding to the detachable components.
9.2, 9.3	13.6	13.6 e), f), h), i), j), l), m), o) are not applicable for devices according to this standard. 13.6 q) is not addressed.

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

Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 8536-11:2004), which has been technically revised with the following changes:

— The former Clause 3 on designation has been deleted;

— Clause 9 on labelling was amended by addition of information regarding the usage of the symbol "XXX" according ISO 7000, symbol 2725;

— Clause 10 on disposal has been added;

— A.4 has been amended;

— The former A.5 specifying a test for leakage of adapters with female and/or male conical fittings has been deleted;

— Normative references and Bibliography have been updated;

— document has been editorially revised.

ISO 8536 consists of the following parts under the general title *Infusion equipment for medical use*:

— *Part 1*: *Infusion glass bottles*

— *Part 2: Closures for infusion bottles*

— *Part 3: Aluminium caps for infusion bottles*

— *Part 4: Infusion sets for single use, gravity feed*

— *Part 5: Burette infusion sets for single use, gravity feed*

— *Part 6: Freeze drying closures for infusion bottles*

— *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*

— *Part 8: Infusion sets for single use with pressure infusion apparatus*

— *Part 9: Fluid lines for single use with pressure infusion equipment*

— *Part 10: Accessories for fluid lines for single use with pressure infusion equipment*

— *Part 11: Infusion filters for single use with pressure infusion equipment*

— *Part 12: Check valves*

The following parts are under preparation:

— *Part 13: Graduated flow regulators for single use with infusion sets*

— *Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*

Infusion equipment for medical use —

Part 11:
Infusion filters for single use with pressure infusion equipment

1 Scope

This part of ISO 8536 applies to sterilized infusion filters for single use used up to 200 kPa (2 bar) on fluid lines of pressure infusion equipment and infusion set as specified in ISO 8536-8. It does not include the effectiveness of filters for separation of particles or germs.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

2 Normative references

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.

ISO 594-2,[1)] *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 8536-4:2010, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Design

The infusion filter housing shall be provided with a venting system to anticipate the blocking of the filter by the accumulation of air bubbles.

4 Materials

The materials from which the infusion filters are manufactured shall comply with the requirements as specified in Clause 5, Clause 6, and Clause 7.

5 Physical requirements

5.1 Transparency

The filter housing shall be transparent. When tested as specified in A.1, the air-water interface shall be detectable.

1) To be replaced by ISO 80369-7.