Irish Standard
I.S. EN ISO 8536-10:2015

Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment (ISO 8536-10:2015)

I.S. EN ISO 8536-10:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

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I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

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This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

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Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-10

June 2015

ICS 11.040.20

Supersedes EN ISO 8536-10:2004

English Version

Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment (ISO 8536-10:2015)

Matériel de perfusion à usage médical - Partie 10 : Accessoires pour tubulures non réutilisables avec un matériel de perfusion sous pression (ISO 8536-10:2015)

Infusionsgeräte zur medizinischen Verwendung - Teil 10: Zubehörteile für Übertragungsleitungen zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO 8536-10:2015)

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

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European foreword

This document (EN ISO 8536-10:2015) 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 8536-10:2004.

In this edition the following changes have been made:

— the former Clause 3 on designation has been deleted;

— Clause 8 on labelling was amended by a note regarding the usage of the symbol “XXX” according ISO 7000-2725;

— Clause 9 on disposal has been added;

— A.4 'Tests for leakage' has been amended;

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

— Normative references and the 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.

EN ISO 8536-10:2015 (E)

Endorsement notice

The text of ISO 8536-10:2015 has been approved by CEN as EN ISO 8536-10:2015 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 8536-4	EN ISO 8536-4:2013 and ISO 8536-4:2013/A1:2013	ISO 8536-4:2010 and Amd.1:2013
ISO 8536-8	EN ISO 8536-8:2015	ISO 8536-8:2015
ISO 8536-12	—	ISO 8536-12:2007 and Amd.1:2012
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, 4.1, 4.2, 4.3, 4.4, 4.5, 4.7, 4.8, Clause 6	7.2	The part of ER 7.2 relating to packaging is not addressed. For packaging see Clause 7 of this standard.
Clause 3, Clause 6	7.3	ER covered by biological evaluation.
4.3, 4.4, 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
4.2, 4.3	7.6	
4.2, 4.3, 4.4	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	
6.1	8.4	Only the sterilisation method is covered
4.2	8.5	
8.2, 8.3	8.7	
4.5, 4.8, 8.2 g)	9.1	The second sentence of ER 9.1 is not addressed
Clause 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.7, 4.8	9.2	

EN ISO 8536-10:2015 (E)

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.3, A.3	12.7.1	Only tensile strength is addressed
Clause 8	13.1	
8.2 d), e), f), g), 8.3 c), d)	13.2	
8.2, 8.3	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 f) Requirement „indication of single use must be consistent across the Community“ is not addressed in the standard 13.3 g), h) is not addressed in the standard
8.2, 8.3	13.4	13.4 is addressed regarding to the label
8.2, 8.3	13.5	13.5 is not addressed regarding to the detachable components
8.2, 8.3	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.

I.S. EN ISO 8536-10:2015

INTERNATIONAL STANDARD

ISO 8536-10

Second edition
2015-06-15

Infusion equipment for medical use —

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

Matériel de perfusion à usage médical —

Partie 10: Accessoires pour tubulures non réutilisables avec un matériel de perfusion sous pression

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.

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 8536-10:2004), which has been technically revised with the following changes:

— The former Clause 3 on designation has been deleted;

— Clause 8 on labelling was amended by a note regarding the usage of the symbol "XXX" according ISO 7000-2725;

— Clause 9 on disposal has been added;

— A.4 'Tests for leakage' 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 the 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 10: Accessories for fluid lines for single use with pressure infusion equipment

1 Scope

This part of ISO 8536 applies to sterilized accessories for single use in fluid lines and pressure infusion equipment as specified in ISO 8536-8.

This part of ISO 8536 includes the following:

a) two-way stopcocks, three-way stopcocks, four-way stopcocks, and stopcocks manifold;

NOTE Designation of a stopcock depends on the number of connections. The number of possible functional positions can be expressed by addition of a complementary note, using a diagonal stroke and a numeral indicating the number of possible stopcock positions, e.g. 3/4-way stopcock for three-way stopcock with four possible positions.

b) units with injection site or check valve;

c) stoppers or adapters.

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

ISO 8536-8, *Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus*

ISO 8536-12, *Infusion equipment for medical use —Part 12: Check valves*

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*

1) To be replaced by ISO 80369-7.