BS EN ISO 8536-11:2015

BSI Standards Publication

Infusion equipment for medical use

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

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National foreword

This British Standard is the UK implementation of EN ISO 8536-11:2015. It supersedes BS EN ISO 8536-11:2004 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 8536-11

June 2015

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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.

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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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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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.

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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 8536-11:2004), 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*

INTERNATIONAL STANDARD ISO 8536-11:2015(E)

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.

5.2 Particulate contamination

The infusion filters shall be manufactured under conditions that minimize particulate contamination. The inner surfaces shall be smooth and clean. When tested as specified in A.2, the number of particles shall not exceed the contamination index.

5.3 Tensile strength

When tested as specified in A.3, the infusion filters shall withstand a static longitudinal tensile force of not less than 15 N for 15 s.

5.4 Leakage

The filter housing shall be impermeable to microorganisms and fluids. The filter membrane, as well as its connection to the housing, shall not burst. When tested as specified in A.4, there shall be no leakage of air or water.

5.5 Adapters with female and/or male conical fittings

Adapters shall be provided with a connector with female conical fitting and/or a connector with male conical fitting according to ISO 594-2.

5.6 Protective caps

ISO 8536-4 applies.

6 Chemical requirements

ISO 8536-4 applies. For test methods, see Annex B.

7 Biological requirements

7.1 Sterility

The infusion filters in their unit container shall have been subjected to a validated sterilization process (see Reference [2] to Reference [5]).

7.2 Pyrogens

The infusion filters shall be assessed for freedom from pyrogens using a suitable test and the results shall indicate that the infusion filters are free from pyrogens. Guidance on testing for pyrogenicity is given in ISO 8536-4.

7.3 Haemolysis

The infusion filters shall be assessed for freedom from haemolytic constituents and the result shall indicate that the infusion filters are free from haemolytic reactions.

Guidance on testing for haemolytic constituents is given in ISO 10993-4.

8 Packaging

ISO 8536-4 applies.

9 Labelling

9.1 General

The labelling shall include the requirements as specified in 9.2 and 9.3. If graphical symbols are used, refer to ISO 15223-1.

NOTE The presence of substances of interest can be indicated by using symbol 2725 of ISO 7000 by replacing the "XXX" by the abbreviation of the substance. The absence of substances of interest can be indicated by crossing the respective symbol.

9.2 Label on unit container

The unit container shall be labelled at least with the following information:

a) name and address of the manufacturer;

b) textual description of the contents, e.g. infusion filter for single use;

c) indication that the infusion filter is free from pyrogens or that the infusion filter is free from bacterial endotoxins;

d) indication that the infusion filter is sterile, using the graphical symbol as given in ISO 15223-1;

e) lot (batch) designation, prefixed by the word LOT, or using the graphical symbol according to ISO 15223-1;

f) year and month of expiration, accompanied by appropriate wording or the graphical symbol according to ISO 15223-1;

g) indication that the infusion filter is for single use only, or equivalent wording, or using the graphical symbol according to ISO 15223-1;

h) instructions for use, including warnings, e.g. about detached protective caps;

i) the letter "P" which stands for pressure and the type, the height of which shall stand out clearly from surrounding text.

If the available space is too small to give all this information in legible characters and/or symbols, the information may be reduced to e) and f). In this case, the information as required in this subclause shall be given on the label of the next bigger shelf or multi-unit container.

9.3 Label on shelf or multi-unit container

The shelf or multi-unit container shall be labelled at least with the following information:

a) name and address of the manufacturer;

b) textual description of the contents, e.g. infusion filter for single use;

c) lot (batch) designation, prefixed by the word LOT, or using the graphical symbol according to ISO 15223-1;

d) year and month of expiration, accompanied by appropriate wording or the graphical symbol according to ISO 15223-1;

e) the letter "P" which stands for pressure and the type, the height of which shall stand out clearly from surrounding text;

f) storage note.

10 Disposal

Information for a secure and environmentally sound disposal of single-use infusion sets should be given.

EXAMPLE "Always dispose of blood contaminated products in a manner consistent with established biohazard procedures."

Annex A
(normative)

Physical tests

A.1 Test for transparency

Fill the infusion filter with distilled water as under usual practice conditions. Visually inspect whether the air-water interface is detectable.

A.2 Test for particulate contamination

The volume of rinse fluid shall be at least 50 times the inner volume of a test specimen. Perform the test as specified in ISO 8536-4.

A.3 Test for tensile strength

Expose the infusion filter to be tested to a static longitudinal tensile force of 15 N for 15 s. Inspect whether points of connection and components withstand the test force applied.

A.4 Test for leakage

A.4.1 In the beginning of the test, the whole system shall be conditioned at the test temperature.

A.4.2 Connect the infusion filter with its openings closed to a compressed air supply using a male and/or female connector in accordance with ISO 594-2. Apply air with an internal excess pressure of 50 kPa to the infusion filter for 15 s. Inspect the infusion filter for any leakage of air under water at (40 ± 1) °C.

A.4.3 Fill the infusion filter with distilled water and apply an internal excess pressure of 200 kPa for 15 min. Inspect the infusion filter for any leakage of water at (40 ± 1) °C.

Annex B
(normative)

Chemical tests

B.1 Preparation of test fluids

Put 10 sterilized ready-to-use infusion filters into a 250 ml wide-neck Erlenmeyer flask. Add 200 ml of distilled water as specified in the current edition of the pharmacopoeia so that all surfaces of the filters are wetted. Cover the flask and keep for 24 h at (37 ± 1) °C. Filters may be disassembled if necessary.

Fill another Erlenmeyer flask with 200 ml of distilled water as specified in the current edition of the pharmacopoeia, cover the flask and keep for 24 h at (37 ± 1) °C. This is used as control fluid for testing according to ISO 8536-4:2010, B.2.

B.2 Test procedures

The tests shall be performed as specified in ISO 8536-4 but using the test fluids as specified in B.1 of this part of ISO 8536.

Annex C
(normative)

Biological tests

ISO 8536-4 applies.

Bibliography

[1] ISO 8536-8, *Infusion equipment for medical use — Part 8: Infusion set for single use with pressure infusion apparatus*

[2] ISO 11135, *Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices*

[3] ISO 11137-1, *Sterilization of health care products — Radiation — Requirements for development, validation and routine control of a sterilization process for medical devices*

[4] ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

[5] ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

[6] EN 15986, *Symbol for use in the labelling of medical devices — Requirements of medical devices containing phthalates*

[7] European Pharmacopoeia

[8] United States Pharmacopeia

[9] Japanese Pharmacopoeia

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