INTERNATIONAL STANDARD

ISO 8536-11

Redline version
compares Second edition to
First edition

Infusion equipment for medical use —

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

Matériel de perfusion à usage médical —

Partie 11: Filtres à perfusion non réutilisables avec un matériel de perfusion sous pression

Reference number
ISO 8536-11:redline:2015(E)

IMPORTANT — PLEASE NOTE

This is a mark-up copy and uses the following colour coding:

Text example 1	— indicates added text (in green)
~~Text example 2~~	— indicates removed text (in red)
	— indicates added graphic figure
	— indicates removed graphic figure
1.x ...	— Heading numbers containg modifications are highlighted in yellow in the Table of Contents

All changes in this document have yet to reach concensus by vote and as such should only be used internally for review purposes.

DISCLAIMER

This Redline version provides you with a quick and easy way to compare the main changes between this edition of the standard and its previous edition. It doesn't capture all single changes such as punctuation but highlights the modifications providing customers with the most valuable information. Therefore it is important to note that this Redline version is not the official ISO standard and that the users must consult with the clean version of the standard, which is the official standard, for implementation purposes.

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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.

~~International Standards are~~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 ~~rules given in~~editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

~~The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.~~

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.

~~ISO 8536-11 was prepared by Technical Committee~~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 ~~equipment~~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 ~~referenced documents~~documents, in whole or in part, are normatively referenced in this document and are indispensable for ~~the application of this document~~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 ~~8536-8~~10993-4, ~~*Infusion equipment for medical use*~~ *Biological evaluation of medical devices — Part ~~8. Infusion equipment for use with pressure infusion apparatus~~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 Designation~~

~~Designation of an infusion filter (IF) for infusions under pressure (P).~~

~~**Infusion filter** ISO 8536-11 — IF — P~~

~~4~~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.

~~5~~4 Materials

The materials from which the infusion filters ~~as given in Clause 3~~are manufactured shall comply with the requirements as specified in ~~Clauses 6~~Clause 5, ~~7~~Clause 6, and ~~8~~Clause 7.

1) To be replaced by ISO 80369-7.

~~6~~5 Physical requirements

~~6.1~~5.1 Transparency

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

~~6.2~~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.

~~6.3~~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.

~~6.4~~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.

~~6.5~~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. ~~When tested as specified in A.5, no water shall leak from the point of connection.~~

~~6.6~~5.6 Protective caps

ISO 8536-4 applies.

~~7~~6 Chemical requirements

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

~~8~~7 Biological requirements

~~8.1~~7.1 Sterility

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

~~8.2~~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.

~~8.3~~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.

~~9~~8 Packaging

ISO 8536-4 applies.

~~10~~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.

~~10.1~~9.2 ~~Unit~~Label on unit container

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

a) name and address of the manufacturer;

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

~~b) indication that the infusion filter is sterile, using the graphical symbol as given in ISO 15223;~~

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 ~~for single use only, or equivalent wording, or~~ sterile, using the graphical symbol ~~according to~~ as given in ISO 15223-1;

~~e) instructions for use, including warnings, e.g. about detached protective caps (instructions for use may also take the form of an insert);~~

~~f~~e) ~~the~~ 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) ~~the wording “Safe for use with pressure infusion equipment” (the name and type of pressure infusion equipment shall be given by the manufacturer)~~ indication that the infusion filter is for single use only, or equivalent wording, or using the graphical symbol according to ISO 15223-1;

h) ~~identification block of designation according to Clause 3 (~~instructions for use, including warnings, e.g. ISO 8536-11 ~~— IF — P)~~ about detached protective caps;

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

~~j) name or logo and address of manufacturer or supplier;~~

~~k) year and month of expiry, accompanied by appropriate wording or the graphical symbol according to ISO 15223.~~

If the available space is too small to give all this information in legible characters and/or symbols, the information may be reduced to ~~f~~e) and ~~k~~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.