INTERNATIONAL STANDARD

ISO 8536-11

Second edition
2015-06-15

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

This document is a preview generated by EVS

Reference number
ISO 8536-11:2015(E)

© ISO 2015

This document is a preview generated by EVS

COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

 © ISO 2015 – All rights reserved

Contents

Page

This document is a preview generated by EVS

© ISO 2015 – All rights reserved

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*

This document is a preview generated by EVS

 © ISO 2015 – All rights reserved

— *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*

This document is a preview generated by EVS

© ISO 2015 – All rights reserved

This document is a preview generated by EVS

Infusion equipment for medical use —

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

This document is a preview generated by EVS

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.

© ISO 2015 – All rights reserved