

This is a preview of "ISO 8536-10:2015". [Click here to purchase the full version from the ANSI store.](#)

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
ISO 8536-10:2015(E)

© ISO 2015



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

This is a preview of "ISO 8536-10:2015". Click here to purchase the full version from the ANSI store.

Contents

	Page
Foreword	iv
1 Scope	1
2 Normative references	1
3 Materials	2
4 Physical requirements	2
4.1 Avoidance of air bubbles.....	2
4.2 Particulate contamination.....	2
4.3 Tensile strength.....	2
4.4 Leakage.....	2
4.5 Adapters with female and/or male conical fittings.....	2
4.6 Protective caps.....	2
4.7 Manipulation of stopcocks.....	2
4.8 Unit with injection site.....	2
4.9 Unit with check valve.....	2
5 Chemical requirements	3
6 Biological requirements	3
6.1 Sterility.....	3
6.2 Pyrogens.....	3
6.3 Haemolysis.....	3
7 Packaging	3
8 Labelling	3
8.1 General.....	3
8.2 Label on unit container.....	3
8.3 Label on shelf or multi-unit container.....	4
9 Disposal	4
Annex A (normative) Physical tests	5
Annex B (normative) Chemical tests	6
Annex C (normative) Biological tests	7
Bibliography	8

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*

This is a preview of "ISO 8536-10:2015". [Click here to purchase the full version from the ANSI store.](#)

- *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*