

This is a preview of "ISO 1135-4:2015". [Click here to purchase the full version from the ANSI store.](#)

Sixth edition
2015-12-01

Transfusion equipment for medical use —

Part 4: Transfusion sets for single use, gravity feed

Matériel de transfusion à usage médical —

Partie 4: Appareils de transfusion non réutilisables à alimentation par gravité



Reference number
ISO 1135-4:2015(E)

© ISO 2015

This is a preview of "ISO 1135-4:2015". Click [here](#) to purchase the full version from the ANSI store.



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 1135-4:2015". Click here to purchase the full version from the ANSI store.

Contents

	Page
Foreword	iv
1 Scope	1
2 Normative references	1
3 General requirements	2
3.1 Nomenclature for components of the transfusion set.....	2
3.2 Maintenance of sterility.....	2
4 Materials	3
5 Physical requirements	3
5.1 Particulate contamination.....	3
5.2 Leakage.....	3
5.3 Tensile strength.....	3
5.4 Closure-piercing device.....	3
5.5 Tubing.....	4
5.6 Filter for blood and blood components.....	4
5.7 Drip chamber and drip tube.....	4
5.8 Flow regulator.....	4
5.9 Flow rate of blood and blood components.....	4
5.10 Injection site.....	5
5.11 Male conical fitting.....	5
5.12 Protective caps.....	5
6 Chemical requirements	5
6.1 Reducing (oxidizable) matter.....	5
6.2 Metal ions.....	5
6.3 Titration acidity or alkalinity.....	5
6.4 Residue on evaporation.....	5
6.5 UV absorption of extract solution.....	5
7 Biological requirements	6
7.1 General.....	6
7.2 Sterility.....	6
7.3 Pyrogenicity.....	6
7.4 Haemolysis.....	6
7.5 Toxicity.....	6
7.6 Assessment of blood component depletion.....	6
7.7 Assessment of damage to blood components.....	6
8 Labelling	7
8.1 General.....	7
8.2 Unit container.....	7
8.3 Shelf or multi-unit container.....	7
9 Packaging	8
10 Disposal	8
Annex A (normative) Physical tests	9
Annex B (normative) Chemical tests	13
Annex C (normative) Biological tests	15
Bibliography	16

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 sixth edition of ISO 1135-4, together with the first edition of ISO 1135-5, cancels and replaces the fifth edition (ISO 1135-4:2012), which has been technically revised with the following changes:

- the scope has been restricted to gravity feed applications and the whole document aligned accordingly;
- transfusion sets for single use used in conjunction with pressure infusion apparatus are now covered by ISO 1135-5;
- 3.3 "Designation examples" has been deleted;
- the Normative references and the Bibliography have been updated;
- some minor editorial changes were introduced in the whole document.

ISO 1135 consists of the following parts, under the general title *Transfusion equipment for medical use*:

- *Part 3: Blood-taking sets for single use*
- *Part 4: Transfusion sets for single use, gravity feed*
- *Part 5: Transfusion sets for single use with pressure infusion apparatus*