This is a preview of "ISO 10555-5:2013". Click here to purchase the full version from the ANSI store.

Second edition 2013-06-15

Intravascular catheters — Sterile and single-use catheters —

Part 5:

Over-needle peripheral catheters

Cathéters intravasculaires — Cathéters stériles et non réutilisables — Partie 5: Cathéters périphériques à aiguille interne



Reference number ISO 10555-5:2013(E)

ISO 10555-5:2013(E)

This is a preview of "ISO 10555-5:2013". Click here to purchase the full version from the ANSI store.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2013

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
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

This is a preview of "ISO 10555-5:2013". Click here to purchase the full version from the ANSI store.

| Contents | | | Page |
|---|--------------------------|--|------|
| Foreword | | iv | |
| 1 | Scope | | 1 |
| 2 | Normat | ive references | 1 |
| 3 | Terms a | and definitions | 1 |
| 4 | Requirements 4.1 General | | 2 |
| | 4.1 (| General | 2 |
| | 4.2 I | Multilumen catheters Physical requirements | 2 |
| | 4.3 I | Physical requirements | 3 |
| | 4.4 I | nformation to be supplied by the manufacturer | 4 |
| Ann | ex A (norm | native) Determination of strength of union of needle hub and needle tube | 5 |
| Annex B (informative) Colours for opaque catheter hubs | | | |
| Annex C (informative) Needle point geometries | | 7 | |
| Annex D (normative) Determination of liquid leakage from vent fitting | | | 8 |
| Rihl | iography | | 10 |

This is a preview of "ISO 10555-5:2013". Click here to purchase the full version from the ANSI store.

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 drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

ISO 10555-5 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 10555-5:1996), which has been technically revised. It also incorporates the Amendment ISO 10555-5:1996/Amd 1:1999 and the Technical Corrigendum ISO 10555-5:1996/Cor 1:2002.

ISO 10555 consists of the following parts, under the general title *Intravascular catheters* — *Sterile and single-use catheters*:

- Part 1: General requirements
- Part 3: Central venous catheters
- Part 4: Balloon dilatation catheters
- Part 5: Over-needle peripheral catheters

The following part is under preparation:

Part 6: Subcutaneous implanted ports

The following part has been withdrawn and the content has been included in ISO 10555-1:

— Part 2: Angiographic catheters

Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters, and to ISO 14972, which specifies requirements for sterile obturators for use with over-needle peripheral catheters.