

This is a preview of "ISO 23908:2011". [Click here to purchase the full version from the ANSI store.](#)

First edition  
2011-06-11

---

---

## **Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling**

*Protection contre les blessures par perforants — Exigences et méthodes d'essai — Dispositifs de protection des aiguilles hypodermiques, des introducteurs pour cathéters et des aiguilles utilisées pour les prélèvements sanguins, non réutilisables*



Reference number  
ISO 23908:2011(E)

© ISO 2011

This is a preview of "ISO 23908:2011". [Click here to purchase the full version from the ANSI store.](#)



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2011

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing 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](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

This is a preview of "ISO 23908:2011". [Click here to purchase the full version from the ANSI store.](#)

## Contents

Page

Foreword .....	iv
Introduction.....	v
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	1
4 Requirements.....	2
4.1 General .....	2
4.2 Activation of the sharps injury protection feature .....	3
4.3 Security of safe mode protection .....	3
5 Test methods .....	3
5.1 General .....	3
5.2 Testing activation of a sharps injury protection feature .....	3
5.2.1 Principle.....	3
5.2.2 Apparatus .....	4
5.2.3 Procedure .....	4
5.3 Challenging the device in safe mode .....	5
5.3.1 General .....	5
5.3.2 Principle.....	5
5.3.3 Apparatus .....	5
5.3.4 Procedure .....	5
5.4 Testing access to the sharp in safe mode .....	6
5.5 Testing simulated clinical use .....	6
5.6 Test report.....	6
6 Information supplied by the manufacturer .....	6
6.1 General .....	6
6.2 Marking/labelling .....	7
6.3 Instructions for use .....	7
Annex A (informative) Guidance on simulated user studies .....	8
Annex B (informative) Method for testing access to the sharp in safe mode .....	10
Bibliography.....	11

## 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 23908 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This is a preview of "ISO 23908:2011". [Click here to purchase the full version from the ANSI store.](#)

## Introduction

This International Standard addresses sharps injury protection systems designed to protect users of medical devices. These sharps injury protection features are intended to prevent, or reduce the potential for, disease transmission which could result from accidental, post-use sharps injuries.

This International Standard is aimed at addressing devices primarily intended for human use, of a wide range of product types, including, among others, hollow-bore needles for injection or infusion of therapeutics into the body, or sampling of fluids from the body, and hollow bore or solid-core needles used for blood sampling (e.g. lancing devices). It addresses sharps injury protection systems which are either active or passive in their activation after the medical device's intended use. It does not cover solid-core needles used for surgery (e.g. suture needles).

Given the broad variation in product design and sharps protection technology, the variety of different types of devices, and in order to avoid unnecessarily restricting innovation, this International Standard has been developed as "horizontal" in nature, which means it provides for general design, testing and labelling requirements, rather than specific physical and prescriptive design requirements. It therefore differs from more "vertical" standards, which list specific maximum forces, detailed test fixture designs, test systems to be used or detailed test measures, as such prescriptive details cannot cover the variety of designs and devices, and may impede continuing innovation in new products, features and/or protection mechanisms that lead to future improvements in healthcare.

This International Standard presumes that the product developer would use a risk-based approach (consistent with ISO 14971) to determine the device design that best meets the needs of a target user population and expected use settings. Through this risk-based approach, the sharps injury protection system would have performance requirements appropriate to the foreseeable risks associated with the intended use of the device, expected user interfaces, and the settings in which these safety features are expected to be used.

This International Standard provides guidelines to enable the manufacturer to verify that the design of the sharps injury protection systems complies with the design intent spelled out in the design specification. As part of this verification, the manufacturer is expected to demonstrate that the performance of the sharps injury protection system is appropriate to the intended users and settings through the use of appropriate simulated or clinical use studies. These simulated or clinical use studies allow the manufacturer to demonstrate that, when used in accordance with the instructions for use, in settings representative of real-life intended use and by intended or foreseeable users, the device functions as intended.

Existing products and those currently under development may not fulfil some of the requirements given by this International Standard. However, manufacturers would be well advised to follow its provisions when improving existing products or developing new products to obtain an even higher level of quality.