

ISO 23908:2024-12 (E)

Sharps injury protection - Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration - Requirements and test methods

Contents

Page

- Foreword..... iv
- Introduction..... vi
- 1 Scope..... 1
- 2 Normative references..... 1
- 3 Terms and definitions..... 1
- 4 Symbols and abbreviated terms..... 3
- 5 Requirements..... 4
 - 5.1 General..... 4
 - 5.2 Activation of the sharps injury protection mechanism..... 5
 - 5.2.1 Active SIPM..... 5
 - 5.2.2 Passive SIPM..... 5
 - 5.3 Security of safe mode protection..... 5
- 6 Test methods..... 6
 - 6.1 General..... 6
 - 6.2 Test procedure and results analysis methodology..... 6
 - 6.3 Testing activation of a sharps injury protection mechanism..... 7
 - 6.3.1 Principle..... 7
 - 6.3.2 Apparatus..... 7
 - 6.3.3 Procedure..... 7
 - 6.4 Challenging the SIPM in safe mode..... 7
 - 6.4.1 General..... 7
 - 6.4.2 Overriding or unlocking test..... 8
 - 6.4.3 Resistance of the SIPM in safe mode to free fall..... 8
 - 6.5 Testing access to the sharp in safe mode..... 9
- 7 Information supplied with the device..... 9
 - 7.1 General..... 9
 - 7.2 Marking/labelling..... 10
 - 7.3 Instructions for use..... 10
- Annex A (normative) Methods for testing access to the sharp in safe mode..... 11
- Annex B (informative) Example of apparatus for performing the free fall test..... 13
- Bibliography..... 14