International

ISO 23908

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

Protection contre les blessures par perforants — Mécanismes de protection des aiguilles à usage unique, des introducteurs pour cathéters et des aiguilles utilisées pour les prélèvements, le contrôle et l'échantillonnage sanguins et l'administration de substances médicales — Exigences et méthodes d'essai

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This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 23908:2011), which has been technically revised.

The main changes are as follows:

— the Scope has been expanded to cover single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration;

— reference has been made to medical devices standards ISO 14971, IEC 62366-1, ISO 11608-1, ISO 20417;

— a free fall test has been added, with as a pass/fail the non-access to the sharps, in order to cover a frequent misuse situation and avoid a potential increase of the risk of sharp injury;

— updates on the test methods Gauge R&R requirements for destructive testing (threshold becoming no greater than 30 % of the specification interval for destructive test, instead of 20 % for any other given measurement);

— a new requirement for A-SIPM has been introduced to include both obvious and non-obvious misuse situations in the risk assessment and to mitigate these situations as far as possible through product design;

— a new requirement has been added to apply a minimum force of 5 N to challenge access to the sharp;

— normative Annex A has been revised to include the methods for testing the access to the sharp in safe mode and after free fall;

— device and SIPM recovery has been added as a potential option to include in the device life cycle.

This document addresses sharps injury protection mechanism designed to protect users and others who can incidentally be exposed to such devices post-use. These sharps injury protection mechanisms are intended to prevent, or reduce the potential risk for, disease transmission which can result from accidental, post-use sharps injuries.

This document addresses devices primarily intended for human use, of a wide range of product types, including but not limited to 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).

Given the broad variation in product design, categories of device, and sharps protection technologies, and in order to avoid unnecessarily restricting innovation, this document has been developed to provide general design, testing and labelling requirements, rather than specific physical and prescriptive design requirements. It therefore differs from documents 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. Including such details can impede continuing innovation in new products, mechanisms and/or protection mechanisms that lead to future improvements in healthcare.

This document presumes that the product developer uses a risk-based approach (consistent with ISO 14971:2019) 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 mechanism 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 sharps injury protection mechanisms are expected to be used.

This document provides guidelines to enable the manufacturer to verify that the design of the sharps injury protection mechanism complies with the design intent spelled out in the design specification.

As part of this validation, the manufacturer is expected to demonstrate that the performance of the sharps injury protection mechanism is appropriate to the intended users and settings through the use of appropriate formative or summative user interface evaluations. These 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 mechanism functions as intended.

The standards ISO 23907-1 (covering single-use sharps containers, revised in 2019), and ISO 23907-2 (covering reusable sharps containers, created in 2019), have significantly improved the prevention of health risks and the safety for all the persons that manipulate post-use sharps medical devices.

However, taking into account the need to intensify the security of sharps medical devices post-use as well as the growing need to reduce their environmental impact by encouraging the possibility of allowing their recycling, this revision constitutes an additional tool for the user’s health protection and the preservation of the environment.