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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 42063-2022

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

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foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1.Structure and Drafting Rules of Standardization Documents"

drafted.

This document is modified and adopted ISO 23908.2011 "Sharps Injury Protection Requirements and Test Methods Single-use hypodermic needles, introduction

Sharps Injury Protection Devices for Introducing Catheter Guide Needles and Blood Sample Collection Needles.

The technical differences between this document and ISO 23908.2011 and their reasons are as follows.

--- Replaced ISO 2859 (all parts) with the normatively cited GB/T 2828 (all parts) (see 5.2.3, 5.3.4) to accommodate

my country's technical conditions to improve operability;

--- Replace ISO 16269-6 (see 5.2.3) with the normatively cited GB/T 3359 to adapt to the technical conditions of our country and improve the availability

operational;

--- Replace ISO 14971 (see Chapter 4) with the normatively cited YY/T 0316-2016 to adapt to the technical conditions of our country,

improve operability;

--- Replace ISO 3951-1 (see 5.2.3, 5.3.4) with the normatively cited GB/T 6378.1 to adapt to the technical conditions of our country,

improve operability;

--- Replaced ISO 3951-4 (see 5.2.3, 5.3.4) with the normatively cited GB/T 6378.4 to adapt to the technical conditions of our country,

Improve operability.

The following editorial changes have been made to this document.

--- Replaced IEC 62366 with YY/T 1474-2016 cited for information (see Note 3 of 4.1.6, Note of 5.4);

--- Replaced ISO 16269-6 with GB/T 3359 cited for information (see 5.2.3 and 5.3.2);

--- Deleted the note in 6.1.

Please note that some content of this document may be patented. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

This document deals with sharps injury protection devices designed to protect users of medical devices. The purpose of these sharps injury protection features is to prevent

Or reduce the potential spread of disease due to accidental, post-instrument sharps injuries.

This document deals with medical devices primarily intended for use by patients, with a wide range of product types, including those used to inject or deliver therapeutic drugs into the body.

Hollow needles, or hollow or solid needles (such as puncture needles) used to take blood samples from the body. The sharps injury protection devices for these medical devices are

Actively or passively activate after use. It does not include solid needles used for surgery (such as suture needles).

Given the wide variation in product design and sharps injury protection technology, the diversity of device types and the need to avoid unnecessary

limitations, this document was drafted in the nature of a collocated standard, which means that it provides general requirements for design, testing and labelling rather than specific objects

management requirements and specified design requirements. Therefore, it differs from dedicated requirements standards, which specify specific maximum force values, detailed test procedures

equipment designs, test systems or detailed test methods, as the details of these regulations cannot cover a wide range of designs and devices and may hinder product,

Continued innovations in functional and/or protective mechanisms that lead to improvements in future healthcare.

This document assumes that product developers will, based on risk analysis (according to

YY/T 0316), determine the

Scene design. Through this risk-based approach, sharps injury protection devices will have a

meet the performance requirements appropriate to the intended use scenario.

This document provides guidelines to enable manufacturers to verify that the design of sharps injury protection devices complies with pre-specified design requirements

beg. As part of validation, manufacturers can be expected to demonstrate sharps injury protection through appropriate simulated use or clinical use studies

The performance of the device is appropriate for the intended user and usage scenario. These simulated use or clinical use studies allow the manufacturer to demonstrate that when in accordance with

When used in the instructions, the device will perform as expected when used by the intended or foreseeable user in a scenario that represents the actual intended use.

function.

Existing products and products in development may not meet certain requirements of this document. However, it is recommended that manufacturers improve existing products or

Follow the provisions of this document when developing new products to achieve a higher level of quality.

Sharps injury protection requirements and test methods

Disposable hypodermic needle, interventional catheter guide needle

Sharps injury protection device for blood sample collection needles

1 Scope

This document specifies the requirements and test methods for evaluating the performance parameters of sharps injury protection devices.

This document applies to single-use hypodermic needles with active or passive sharps injury protection devices, introducer needles for interventional catheters,

Blood sample collection needle. Sharps injury protection devices can be integrated with the product or combined with the product prior to use for sharps injury protection

Function.

This document does not address requirements for the storage and handling of sharps injury protection devices prior to their intended use, nor does it address requirements for the medical device itself.

Require.

2 Normative references

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, dated citations

documents, only the version corresponding to that date applies to this document; for undated references, the latest edition (including all amendments) applies to

this document.

GB/T 2828 (all parts) Count sampling inspection procedure [ISO 2859 (all parts)]

Note. GB/T 2828.1 Counting Sampling Inspection Procedure Part 1.Lot-by-Lot Inspection Sampling Plan Retrieved by Acceptance Quality Limit (AQL) (GB/T 2828.1-

2012, ISO 2859-1.1999, IDT);

GB/T 2828.2 Counting Sampling Inspection Procedures Part 2.Isolated Lot Inspection Sampling Plans Retrieved by Limiting Quality (LQ) (GB/T 2828.2-

2008, ISO 2859-2.1985, NEQ);

GB/T 2828.3 Counting Sampling Inspection Procedure Part 3.Skipping Batch Sampling Procedure (GB/T 2828.3-2008, ISO 2859-3.2005, IDT);

GB/T 2828.4 Counting Sampling Inspection Procedures Part 4.Assessment Procedures for Claimed Quality Levels (GB/T 2828.4-2008, ISO 2859-4.

2002,MOD);

GB/T 2828.5 Counting sampling inspection procedures - Part 5.Lot-by-lot sequential sampling inspection system retrieved by acceptance quality limit (AQL)

(GB/T 2828.5-2011, ISO 2859-5.2005, IDT);

GB/T 2828.10 Counting Sampling Inspection Procedure Part 10.GB/T 2828 Counting Sampling Inspection Series Standard Guide (GB/T 2828.10-

2010, ISO 2859-10.2006, MOD).

GB/T 3359 Statistical processing and interpretation of data Determination of statistical tolerance intervals (GB/T 3359-2009, ISO 16269-6.

2005, IDT)

GB/T 6378.1 Metrological sampling inspection procedure Part 1.Retrieved by acceptance quality limit (AQL) for single quality characteristics and single quality characteristics

One-time sampling plan for batch-by-batch inspection of AQL (GB/T 6378.1-2008, ISO