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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0573.3-2025

Replacing YY/T 0573.3-2019

**Sterile hypodermic syringes for single use - Part 3:
Auto-disable syringes for fixed dose immunization**

一次性使用无菌注射器 第3部分：自毁型固定剂量疫苗注射器

(English Translation)

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Foreword

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

Drafting.

This document is Part 3 of YY/T 0573 "Disposable Sterile Syringes". YY/T 0573 has already published the following parts.

- Part 2: Syringes for Powered Injection Pumps;
- Part 3: Self-Destructing Fixed-Dose Vaccine Injector;
- Part 4: Preventing the reuse of syringes.

This document replaces YY/T 0573.3-2019. Compared with YY/T 0573.3-2019, apart from structural adjustments and editorial changes, the main differences are...

The technological changes are as follows.

- The scope has been changed (see Chapter 1, Chapter 1 of the 2019 edition);
- Several terms and definitions have been added (see Chapter 3);
- Table 1 has been revised (see Table 1, 2019 version);
- The baseline requirements have been changed (see 5.5.4, version 5.5.4 of 2019);
- The requirements for non-integral needles have been changed (see 5.6.2, version 5.6.2 of 2019);
- The self-destruct feature requirements have been changed (see 5.9, version 5.9 of 2019);
- The requirements for sharps injury protection have been changed (see 5.10, version 5.10 of 2019);
- The requirements for test reports have been changed (see Appendix G.4, Appendix E.4

of the 2019 edition);

---Appendix H has been amended (see Appendix H, Appendix F of the 2019 edition).

This document is modified to adopt ISO 7886-3:2020 "Disposable sterile syringes - Part 3: Self-destructing fixed-dose vaccine injection".

Instrument.

This document has undergone significant structural adjustments compared to ISO 7886-3:2020. A comparison of the structural numbering changes between the two documents is provided below.

See Appendix A for the table.

This document differs significantly from ISO 7886-3:2020 in several technical aspects. The relevant clauses are indicated in vertical margins.

Single lines (|) are indicated. A summary of these technical differences and their causes can be found in Appendix B.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Syringes (Needles) (SAC/TC95).

Introduction

YY 0573 "Disposable Sterile Syringe" is proposed to consist of three parts.

---Part 2: Syringes for Powered Injection Pumps. This section aims to specify the specific requirements for syringes used in powered injection pumps.

---Part 3: Self-destructing fixed-dose vaccine syringes. Designed for self-destructing fixed-dose syringes that are no longer intended for use after a predetermined dose has been administered.

Regulations were established for the use of vaccine syringes.

---Part 4: Prevention of Syringe Reuse. This aims to cover situations where syringes are not reused during, after, or after the intended dose has been administered.

The syringe used in the procedure.

This document does not cover provisions for preventing injury from syringe needle tips.

This document does not specify design requirements for self-destruct features; these are to be determined by the manufacturer.

This document does not address the compatibility of the injected medication/vaccine with self-destructing fixed-dose vaccine syringes.

This document is modified to adopt ISO 7886-3:2020. The structural adjustments to the international standard are shown in Appendix A, and the technical differences and reasons are shown in Appendix B.

Disposable sterile syringes Part 3: Self-Destructing Fixed-Dose Vaccine Injector

1 Scope

This document specifies the use of disposable sterile syringes (hereinafter referred to as syringes) that automatically deactivate upon delivery of a preset vaccine dose.

The characteristics and performance of the device.

This document applies to needle- or needleless injection devices made of plastic, rubber, or other materials intended for aspiration or immediate post-injection of vaccines.

Disposable sterile syringes for needles.

This document does not apply to insulin injectors, syringes for power-driven infusion pumps, syringes designed to prevent reuse, or syringes with inconsistent dosage self-destruction mechanisms.

Type-fed syringes and pre-filled syringes.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

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

This document.

GB/T 191 Pictorial Symbols for Packaging and Storage (GB/T 191-2008, ISO 780:1997, MOD) GB/T 6682 Specifications and test methods for water used in analytical laboratories (GB/T 6682-2008, ISO 3696:1987, MOD) GB/T 14233.1-2022 Medical infusion, transfusion and injection equipment test methods - Part 1: Chemical analysis methods GB/T 14233.2 Test methods for medical infusion, transfusion and injection equipment - Part 2: Biological test methods GB 15810-2019 Disposable sterile syringes (ISO 7886-1:2017, MOD) GB 15811-2016 Single-use sterile injection needles (ISO 7864:1993, NEQ) GB/T 18457 Stainless steel needles for manufacturing medical devices (GB/T 18457-2015, ISO 9626:1991, MOD) GB/T 42063 Requirements and test methods for protection against sharps injuries. Single-use hypodermic needles, interventional catheter guide needles, and

blood samples.

Sharps protection device for sampling needle (GB/T 42063-2022, ISO 23908:2011, MOD)
YY/T 0466.1 Symbols for medical devices used to provide information to manufacturers -
Part 1: General requirements (YY/T 0466.1-2023, ISO 15233-1:2021, MOD) YY/T 0916.7
Small-bore connectors for medical liquids and gases - Part 7: Connectors for intravascular
or subcutaneous applications (YY/T 0916.7-2024, ISO 80369-7:2021, IDT)

3 Terms and Definitions

The following terms and definitions apply to this document.

When the preset fixed dose is injected, the self-destruct feature automatically activates to prevent the reuse of the syringe and needle.