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

YY/T 1768.1-2021

**Needle-based injection systems for medical use - Requirements
and test methods - Part 1: Needle-based injection systems
(English Translation)**

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Foreword

YY/T 1768 "Needle-based injection systems for medical use - Requirements and test methods" consists of the following parts.

- Part 1.Needle-based injection systems;
- Part 2.Needles;
- Part 3.Containers;
- Part 4.Electronic and electromechanical pen injectors;
- Part 5Automatic functions;
- Part 7.Accessibility services for the visually impaired.

This Part is Part 1 of YY/T 1768.

This Part was drafted in accordance with the rules given in GB/T 1.1-2009.

This Part uses redrafting method to refer to ISO 11608-1.2014 "Needle-based injection systems for medical use - Requirements and test methods - Part 1.Needle-based injection systems". The degree of conformity with ISO 11608-1.2014 is non-equivalent. Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights.

This Part was proposed by National Medical Products Administration.

This Part shall be under the jurisdiction of National Technical Committee on Medical Syringe (Needle) of Standardization Administration of China (SAC/TC 95).

The drafting organizations of this Part. Shandong Weigao Group Medical Polymer Products Co., Ltd., Shanghai Medical Device Testing Institute, China National Institute for Food and Drug Control, Novo Nordisk (China) Pharmaceutical Co., Ltd., Shanghai Food and Drug Administration Certification and Evaluation Center.

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1 Scope

This Part of YY/T 1768 specifies the requirements and test methods for needle-based injection systems.

This Part applies to needle-based injection systems intended for use with needles and containers, such as pen injectors.

The containers described in this Part include single-dose, multi-dose syringe systems and cartridge systems filled by the manufacturer or end user.

This Part does not apply to needleless syringes.

This Part does not address requirements and related methods for filling containers and appliances by the end user.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 2423.4-2008, Environmental testing for electric and electronic products - Part

2 Test method - Test Db. Damp heat, cyclic (12 h + 12 h cycle) (IEC 60068-2-

30.2005, IDT)

GB/T 2423.10-2019, Environmental testing - Part 2. Test methods - Test Fc.

Vibration (sinusoidal) (IEC 60068-2-6.2007, IDT)

GB/T 3359-2009, Statistical interpretation of data - Determination of statistical tolerance intervals (ISO 16269-6.2005, IDT)

GB/T 16886.1, Biological evaluation of medical devices - Part 1. Evaluation and testing within a risk management process (GB/T 16886.1-2011, ISO 10993-1.2009, IDT)

GB/T 18779.1, Geometrical Product Specifications (GPS) - Inspection by measurement of workpieces and measuring equipment - Part 1. Decision rules for proving conformance or non-conformance with specifications (GB/T 18779.1-2002, eqv ISO 14253-1:1998)

3.1 Terms and definitions

The following terms and definitions apply to this document.

3.1.1 cap

A component used in a needle-based injection system to protect the syringe and its contents.

3.1.2 container

A primary packaging that contains injectable drug product (single or multi-chamber).

3.1.6 "dose delivered" indication

The number displayed in the dose window indicating the dose of the drug product to be delivered.

3.1.7 manufacturer-filled

A container that is prefilled with a drug by a drug manufacturer and is supplied to a user.

3.1.8 minimum deliverable dose

The manufacturer ensures that in a single-dose manufacturer-filled needle-based injection system, the minimum dose delivered is designed to the one that can empty the container.

3.1.9 needle-based injection system

An injection system for injecting parenteral drugs through the use of a needle and a multi-dose or single-dose container.

3.1.12 user packaging

A package or set of identical needle-based injection systems from the same manufacturing lot provided to the user, including instructions for use.