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

YY/T 0285.5-2018

**Intravascular catheters-Sterile and single-use catheters--Part 5:
Over-needle peripheral catheters
(English Translation)**

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Foreword

YY 0285 "Intravascular Catheter Disposable Sterile Catheter" is divided into the following parts:

- Part 1: General requirements;
- Part 3: Central venous catheters;
- Part 4: Balloon dilatation catheters;
- Part 5: Trocar peripheral catheter:

This part is the fifth part of YY 0285:

The following parts have been withdrawn and have been included in Part 1:

- Part 2: Contrast catheter:

This section is drafted in accordance with the rules given in GB/T 1.1-2009:

This Part replaces YY 0285.5-2004 "Single-use Sterile Intravascular Catheters Part 5: Trocar Peripheral Catheters", and Compared with YY 0285.5-2004, the main revisions are as follows:

- Modified the normative reference documents;
- Deleted Appendix A:

This part uses the redrafted law to revise and adopt ISO 10555-5:2013 "Intravascular catheters for single-use sterile catheters Part 5 Subsection: Trocar Peripheral Catheters":

The technical differences between this part and ISO 10555-5:2013 and the reasons are as follows:

- Regarding the normative reference documents, this standard has made adjustments with technical differences to adapt to the technical conditions of our country and the adjustment situation the situation is reflected in Chapter 2 "Normative References", and the specific adjustments are as follows:

- Replaced ISO 594-1 with GB/T 1962.1, which is equivalent to the international standard;
- Replaced ISO 9626 with GB/T 18457, which is equivalent to the international standard;
- Replacing ISO 10555-1 with YY 0285.1 which adopts the international standard:

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying these patents:

This part is proposed by China Food and Drug Administration:

This part is under the jurisdiction of the National Standardization Technical Committee of Medical Infusion Sets:

1 Scope

This part of YY 0285 specifies the blood trocars supplied in a sterile state and used for single use for insertion into the peripheral vascular system in-line catheter requirements:

2 Normative references

The following documents are indispensable for the application of this document: For dated references, only the dated version applies to this document pieces: For undated references, the latest version (including all amendments) applies to this document:

GB/T 1962.1 Syringes, injection needles and other medical devices 6% (Luer) conical fittings Part 1: General requirements (GB/T 1962.1-2015, ISO 594-1:1986, IDT) GB/T 18457 Manufacture of stainless steel needle tubes for medical devices (GB/T 18457-2015, ISO 9626:1991, MOD) YY 0285.1 Intravascular Catheters Sterile Disposable Catheters Part 1: General Requirements (YY 0285.1-2017, ISO 10555-1:2013, MOD)

3 Terms and Definitions

The following terms and definitions defined in YY 0285.1 apply to this document:

A catheter used to introduce or remove fluids or devices from the peripheral vasculature:

needle

An assembly including at least one needle tube and a hub that fixes it and communicates with it: see picture 1:

needle tube

A rigid tube that is cut at one end to facilitate entry into body tissue:

needle hub

The connector for fixing the needle tube, the inner hole of which communicates with the

needle tube:

Exhaust joint ventfitting A fitting used to vent gas while restricting or preferably preventing the outflow of blood: Divided into two kinds of fixed or movable:

catheter assembly catheterunit an assembly consisting of catheter tubing, a catheter adapter, and any integral connectors: see picture 1:

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