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

YY/T 0802.2-2024

Replacing YY/T 0802-2020

**Processing of medical device - Information to be provided by
the medical device manufacturer - Part 2: Non-critical medical
devices**

医疗器械的处理 医疗器械制造商提供的信息 第2部分：低度危险性医疗器械
(English Translation)

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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 for standardization documents" Drafting.

This document is Part 2 of YY/T 0802 "Handling of medical devices - Information provided by the medical device manufacturer".

The following parts have been published.

--- Part 1: Medium and high risk medical devices;

--- Part 2: Low-risk medical devices.

This standard replaces YY/T 0802-2020 "Processing of medical devices - Information provided by medical device manufacturers" and is consistent with YY/T 0802-Compared with 2020, in addition to structural adjustments and editorial changes, the main technical

changes are as follows.

- Changed the scope (see Chapter 1, Chapter 1 of the 2020 edition);
- Added the terms and definitions "cleaning factor" and "clinical use" (see 3.2, 3.3);
- Changed the content of the confirmation of processing in the information (see Chapter 4, Chapter 4 of the 2020 edition);
- Changed the content of risk analysis (see Chapter 5, Chapter 5 of the 2020 edition);
- Changed the content of information to be provided by medical device manufacturers (see Chapter 6, Chapter 6 of the 2020 edition).

This document is modified to adopt ISO 17664-2:2021 "Processing of medical devices - Information provided by medical device manufacturers on the processing of medical devices".

Information Part 2: Low-risk medical devices.

This document has the following structural adjustments compared to ISO 17664-2:2021.

- Chapter 4 corresponds to Chapter 5 of ISO 17664-2:2021;
- Chapter 5 corresponds to Chapter 4 of ISO 17664-2:2021;
- Appendix C corresponds to Appendix E in ISO 17664-2:2021;
- Appendix D corresponds to Appendix C in ISO 17664-2:2021;
- Appendix E corresponds to Appendix D in ISO 17664-2:2021.

The technical differences between this document and ISO 17664-2:2021 and their reasons are as follows.

- Deleted the term and definition "3.7 Medical device" to coordinate with regulations.

The following editorial changes were made to this document.

- Deleted some examples of medical devices that can be automatically cleaned;
- Added reference ISO 11139:2018 as the source of terms and definitions.

Introduction

YY/T 0802 "Information provided by medical device manufacturers for the treatment of medical devices" is a document concerning information provided by medical device manufacturers for the treatment of medical devices.

YY/T 0802 is intended to provide medical device manufacturers with information on the processing of medical devices. It consists of two parts.

constitute.

--- Part 1: Medium and high risk medical devices. The purpose is to provide medical device manufacturers with medium and high risk medical devices processing information.

--- Part 2: Low-risk medical devices. The purpose is to provide medical device manufacturers with treatment of low-risk medical devices.

Management information.

This document is applicable to manufacturers of medical devices that require processing by processors for post-use. These medical devices include.

---Medical products that are used repeatedly and need to be processed to transform them from the state after clinical use to the state ready for the next use instrument;

---Disposable medical devices need to be processed before use and used in a clean and/or sterilized state.

With the remarkable progress of science and technology, more and more complex medical devices are developed and applied to patients' health care.

Advances in device design may also make the device more difficult to clean and sterilize.

Cleaning and sterilization technology has undergone significant changes over the past decade, with new systems and methods being continually applied to the processing of medical devices.

At the same time, there is a greater awareness that validation is necessary to ensure that medical devices are effectively processed, including cleaning and/or sterilization.

Therefore, medical device manufacturers are required to provide sufficient information to support end users in using effective equipment and processes to test medical devices.

Safe and effective processing.

Detailed instructions for handling medical devices are provided to minimize the risk of transmission of infectious agents. In addition, effective handling can Minimize adverse effects on medical devices.

Cleaning is an important step to ensure that used medical devices can be used safely again.

If the tissue, microorganisms, detergents and lubricants are not removed completely, it will affect the next disinfection process or damage the normal function of the medical device.

Yes. Disposable medical devices provided by medical device manufacturers for pre-use processing may also need to be processed before further processing.

Cleaning.

After cleaning, other factors can also affect the safe and effective use of medical devices. For example, inspection and functional testing procedures may need to be ensured.

To ensure that medical devices do not pose safety risks when used, medical device manufacturers provide instructions to help users perform inspections and tests.

Manufacturers of medical devices that are to be disposed of have a responsibility to ensure that the design of the medical device enables it to be effectively disposed of.

Considerations for commonly used and validated treatment methods are given in Appendix A as examples. Appendices A and B can serve as a guide and refer to.

Processing of medical devices provided by medical device manufacturers Information Part 2: Low-risk medical devices

1 Scope

This document specifies the information provided by medical device manufacturers regarding the handling of low-risk medical devices (i.e. medical devices that only come into contact with intact skin).

information requirements for medical devices that do not directly contact the patient.

This document applies to information that is processed prior to use or reuse of medical devices.

This document does not define processing instructions, but rather specifies the requirements for medical device manufacturers to provide detailed processing instructions.

The process includes the following applicable steps.

- a) Preparation before treatment;
- b) cleaning;
- c) disinfection;
- d) drying;
- e) inspection and maintenance;
- f) packaging;
- g) storage;
- h) Transportation.

This document does not apply to the handling of the following items.

- a) Medium to high risk medical devices;
- b) medical devices intended for sterilization;