

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

YY/T 0802.1-2024

**Processing of medical device - Information to be provided by
the medical device manufacturer - Part 1: Critical and
semi-critical medical devices**

(English Translation)

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Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020

Directives for standardization - Part 1.Rules for the structure and drafting of
standardizing documents.

This document is part 1 of YY/T 0802 Processing of medical device - Information to be
provided by the medical device manufacturer. YY/T 0802 has been published in the
following parts.

-- Part 1.Critical and semi-critical medical devices;

-- Part 2.Non-critical medical devices.

This document replaces YY/T 0802-2020 Processing of medical devices - Information
to be provided by the medical device manufacturer. Compared with YY/T 0802-2020,
in addition to structural adjustments and editorial changes, the main technical changes
are as follows.

-- The scope has been changed (see Chapter 1; see Chapter 1 of the 2020 edition);

-- The term and definition of "medical device manufacturer" have been changed
(see 3.5; see 3.5 of the 2020 edition);

-- The content of the processing instructions has been changed (see 6.2; see 6.2 of

the 2020 edition);

-- The content of immediate on-site treatment after use has been changed (see 6.4; see 6.4 of the 2020 edition);

This document is modified in relation to ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices.

The technical differences between this document and ISO 17664-1:2021 and their reasons are as follows.

-- The term and definition "3.5 medical device" have been deleted to coordinate with regulations.

The following editorial changes were made to this document.

-- The note to the term and definition of "3.5 medical device manufacturer" has been deleted.

Processing of medical device - Information to be provided by the medical device manufacturer - Part 1: Critical and semi-critical medical devices

1 Scope

This document specifies the requirements for information to be provided by medical device manufacturers regarding the processing of critical and semi-critical medical devices (i.e., medical devices that enter normally sterile areas of the human body, or medical devices that contact mucous membranes or non-intact skin) or medical devices that are to be sterilized.

This document applies to information on the processing prior to the use or reuse of medical devices.

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

a) immediate on-site processing after use;

- b) preparation before cleaning;
- c) cleaning;
- d) disinfection;
- e) drying;
- f) inspection and maintenance;
- g) packaging;
- h) sterilization;
- i) storage;
- j) Transportation.

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

-- Non-critical medical devices that are not intended to be sterilized;

A documented procedure for obtaining, recording and interpreting the results necessary to determine that a process consistently produces product conforming to predetermined specifications.

3.20 verification

To confirm by providing objective evidence that specified requirements have been met.

[Source. ISO 9000.2015, 3.8.13, modified]

3.21 washer-disinfectors; WD

Equipment that is expected to clean and disinfect items.

[Source. ISO 11139.2018, 3.319, modified]

4.1 The medical device manufacturer shall validate each processing step in the information provided with the medical device. Validation shall confirm that each processing step is appropriate.

4.2 The medical device manufacturer shall provide objective evidence that the validation of processing has been performed to demonstrate that the medical device will be clean, disinfected and/or sterilized after processing in the specified sequence.

NOTE 1: In addition to the manufacturer's obligation to prove the validity of the information provided,

the relevant management department can also require the processor to verify the final validity of the processing.

NOTE 2: The relevant management department may allow or require the use of other methods for processing. In this case, it is usually necessary for the processor to confirm the effectiveness of the processing method.

4.3 If different medical devices provided by the manufacturer have common properties,

their validation can be carried out as a product family. If this approach is adopted, the medical device manufacturer shall confirm the commonalities between the different medical devices and consider the most unfavorable state of the product family in the validation.

NOTE: See C.1 in Appendix C.

5 Risk analysis

Medical device manufacturers shall conduct risk analysis to determine the content and