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

YY/T 1960-2025

**Medical devices - Information to be supplied by the
manufacturer**

(English Translation)

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1 Scope

This document specifies the requirements for information to be supplied by the manufacturer of medical devices or accessories. This document includes generally applicable requirements for the marking and labeling of medical devices or accessories on their own and their packaging, as well as the identification and accompanying information of medical devices or accessories. This document does not specify the method of providing information.

The requirements of medical device product standards or group standards take precedence over the requirements of this document.

Note 1: See Annex A, A.2 for the guidelines or instructions for this clause.

Note 2: The requirements for the labeling, marking, and accompanying documentation of medical devices or accessories - as imposed by certain regulatory authorities with jurisdiction - may differ from those in this document.

2 Normative references

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

GB/T 2659.1, Codes for the representation of names of countries and their subdivisions

- Part 1. Country code (GB/T 2659.1-2022, ISO 3166-1.2020, MOD)

GB/T 2893.1, Graphical symbols - Safety colours and safety signs - Part 1. Design principles for safety signs and safety markings (GB/T 2893.1-2013, ISO 3864-1.2011, MOD)

GB/T 7408.1, Date and time - Representations for information interchange - Part 1.

Basic rules (ISO 8601.2019, IDT)

GB/T 42061-2022, Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13458.2016, IDT)

GB/T 42062-2022, Medical devices - Application of risk management to medical devices (ISO 14971.2019, IDT)

YY/T 0466.1-2023, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1. General requirements (ISO 15223-1.2021, IDT)

ISO 7000, Graphical symbols for use on equipment - Registered symbols

ISO 7010.2019, Graphical symbols - Safety colours and safety signs - Registered safety signs

ISO 80000-1, Quantities and units - Part 1. General

IEC 60417 (database), Graphical symbols for use on equipment

IEC 62366-1.2015, Medical devices - Part 1. Application of usability engineering to medical devices

3 Terms and definitions

For the purpose of this document, terms and definitions given in GB/T 42061-2022,

GB/T 42062-2022 and IEC 62366-1.2015, as well as the following apply.

3.1

accessory

An article specifically designed by the manufacturer for use with one or more medical devices, enabling or assisting in the use of those medical devices as intended.

Note 1: An accessory is typically a consumable or an individual item used with one or more medical devices.

Note 2: Some regulatory authorities with jurisdiction consider accessory to be a medical device.

Note 3: Some regulatory authorities with jurisdiction have a different definition for accessory.

Note 4: The definition of accessory in GB 9706.1 is as follows.

An accessory refer to the additional part used together with the equipment, so as to.

-- achieve intended use;

-- make the equipment suitable for certain specific purposes;

symbol

Illustrations displayed on medical device labels and/or related documents for conveying characteristic information, not requiring the information provider or recipient to have language knowledge of a specific country or ethnicity.

Note: Symbols may be abstract patterns or illustrations, or common object graphics, including letter or number characters with a good reason.

[Source. YY/T 0466.1-2023, 3.18]

3.30

technical description

Part of the accompanying information for guiding responsible parties and service personnel, which is essential for preparing for the initial use and safe use, maintenance or repair of medical devices or accessories, as well as for their processing, transport and storage throughout their expected lifetime.

Note 1: The technical description may be included in the instruction for use.

Note 2: See Figure 1 as an example.

3.31

UDI data carrier unique device identifier data carrier

Data media for storing or transmitting the unique identifier of a medical device.

Note: UDI data carrier may include one-dimensional/linear barcodes, two- dimensional/matrix barcodes, radio frequency identification (RFID), etc.

[Source. YY/T 1681-2019, 4.1, modified]

4 General

The information supplied by the manufacturer typically takes the following aspects into consideration.

a) The risk management process in GB/T 42062-2022 and the usability engineering process in IEC 62366-1.2015 should be used to determine the information (including information for safety) provided in the information supplied by the manufacturer.

Note 1: Medical device-specific standards may require manufacturers to provide additional information.

b) If this document specifies a particular version of a normative reference, the manufacturer may substitute it with a newer version, provided that the manufacturer can demonstrate that the residual risks arising from the substitution remain acceptable and are comparable to those arising from the application of the particular version of the normative reference.

c) The information supplied by the manufacturer shall be in a language appropriate for the intended users.

Note 2: Regulatory authorities with jurisdiction may impose requirements on the language chosen for the information supplied by the manufacturer.

d) The accompanying information shall specify.

1) Any professional skills, training, and expertise required by the intended user or responsible party, which are necessary to achieve the intended use of the medical device;

2) If applicable, restrictions on the intended use environment of the medical device.

e) Information supplied by the manufacturer shall be written and presented in terms that are easy for the intended user to understand, taking into account their education, training and any special needs where appropriate.

Note 3: Medical device-specific standards may require additional usability requirements.

Check for compliance by reviewing the information supplied by the manufacturer.

5.1 Units of measurement

In the information supplied by the manufacturer, the units of measurement used.

a) The numerical display of parameters in the information supplied by the manufacturer shall be expressed as follows.

1) the International System of Units (SI) as defined in ISO 80000-1;

2) any other unit required by relevant group standards or product standards;