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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0466.1-2023

Replacing YY/T 0466.1-2016

Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

医疗器械 用于制造商提供信息的符号 第1部分：通用要求

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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 0466 "Medical devices - Symbols to be used with information to be supplied by the manufacturer". YY/T0466 has released the following parts:

- Part 2: Symbol development, selection and validation.

This document replaces YY/T 0466.1-2016 "Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements". Compared with YY/T 0466.1-2016, except for structural adjustments and editorial changes, the main technical changes are as follows:

a) ADD the terms "accompanying information" (see 3.1), "catalogue number" (see 3.2), "distributor" (see 3.4), "importer" (see 3.5), "information supplied by the manufacturer" (see 3.6), "instructions for use" (see 3.7), "lot number" (see 3.9), "manufacturer" (see 3.10), "marking" (see 3.11), "model number" (see 3.12), "risk" (see 3.13), "serial number" (see 3.14), "single patient multiple use" (see 3.15), "single use" (see 3.16), "sterile" (see 3.17), "symbol" (see 3.18);

b) DELETE the terms "characteristic information" (see 3.1 of the 2016 edition), "marking" (see 3.4 of the 2016 edition), "symbols used for marking medical devices" (see 3.5 of the 2016 edition), "title" (see 3.6 of the 2016 edition);

c) CHANGE the definition of the term "label" (see 3.8, 3.3 of the 2016 version);

d) In Table 1, ADD 19 symbols confirmed in accordance with YY/T 0466.2 and 6 registered symbols in ISO 7000, ISO 7001 or IEC 60417. DELETE the column of "Additional requirements". CHANGE the header of the last column "ISO 7000 registration number" into "ISO/IEC symbol number and registration date". ADD the registration date to all registered symbols (see Table 1; Table 1 of the 2016 edition);

e) CHANGE the description, requirements, notes of symbol 5.1.1 in Table 1 (see f) CHANGE the title of symbol 5.1.2 in Table 1 "EU authorized representative" into "European community/EU authorized representative", changing the requirements and notes (see 5.1.2; 5.1.2 in the 2016 edition);

h) CHANGE the title "lot code" of symbol 5.1.5 in Table 1 into "lot number" (see i) CHANGE the title "serial number" of symbol 5.1.7 in Table 1 into "serial No."

j) CHANGE the title "non-aseptic" in symbol 5.2.7 in Table 1 into "non-sterile" (see k) CHANGE the title of symbol 5.2.8 in Table 1 "Do not use if the packaging is damaged" into

"Do not use if the packaging is damaged and consult the instructions for use", changing the instructions and notes (see 5.2.8; 5.2.8 of the 2016 edition);

"Avoid sun exposure and radiation", changing the note (see 5.3.3; 5.3.3 of the 2016 edition);

n) CHANGE the title of symbol 5.4.2 in Table 1 "No secondary use" into "No reuse" (see 5.4.2; 5.4.2 of the 2016 edition);

o) CHANGE the symbol 5.4.3 "Check the instructions for use" in Table 1 into "Check the instructions for use, electronic instructions for use" (see 5.4.3; 5.4.3 of the 2016 edition);

r) CHANGE the title "liquid path" of symbol 5.6.2 in Table 1 into "fluid path" (see s) CHANGE the title "liquid filter pore size" of symbol 5.6.5 in Table 1 into "liquid filter with pore size" (see 5.6.5; 5.6.5 of the 2016 edition);

t) ADD examples of using symbols to Appendix A.

This document modifies and adopts ISO 15223-1:2021 "Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements".

The technical differences between this document and ISO 15223-1:2021, as well as their reasons, are as follows:

- USE the normative reference GB/T 2659.1 to replaced ISO 3166-1, to adapt to China's technical conditions, thereby increasing operability;

- USE the normative reference YY/T 0466.2 to replaced ISO 15223-2, to adapt to China's technical conditions, thereby increasing operability;

- CHANGE the definition and origin of the term "importer" (see 3.5), to keep "medical device" is defined in medical device regulations and standards, so it is not repeated in this document;

Please note that some contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document shall be under the jurisdiction of the National Medical Device Quality Management and General Requirements Standardization Technical Committee (SAC/TC 221).

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- It was revised for the first time into a sub-part standard in 2009; this document

- It was revised for the second time in 2016;

- This is the third revision.

Introduction

Medical device manufacturers and other parties in the supply chain are required to provide specific information on the medical device, on its packaging or in accompanying information. For simplicity and to avoid text translation, this information is provided by symbols with specific meanings. This document does not specify the information that needs to be provided, only the internationally recognized symbols used to provide this specific information are specified.

The symbols included in this document have been published in ISO 7000, ISO 7001, IEC 60417, OR have gone through a formal symbol validation process.

This document is intended for use by medical device manufacturers selling products in countries with specific language requirements. These symbols achieve a consistent description of the information. This document may also be used by customers or endusers of medical devices, who obtain medical devices from many sources and may have varying language abilities.

YY/T 0466 "Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied" is divided into two parts.

- Part 1: General requirements. The purpose is to propose requirements for the formulation and use of symbols that express medical device information, AND to provide internationally recognized symbols that meet the requirements.

- Part 2: Symbol development, selection and validation. The purpose is to formulate, select, and confirm the symbols to be included in YY/T 0466.1, to ensure that these symbols are easy to understand by the target group.

In this document, the following auxiliary verbs are used:

- "May/could" means possibility or ability;

- "Must" means external constraints that are not required by this document.

Information marked with "Note" is intended to assist in understanding or using this document. The "Note" used in Chapter 3 provides additional information that supplements