ICS 01.080.20; 11.040.01

CCS C 37

YY

PHARMACEUTICAL INDUSTRY 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

(ISO 15223-1:2021, MOD)

Issued on: September 05, 2023 **Implemented on: September 15, 2025**

Issued by: National Medical Products Administration

Table of Contents

Foreword 3

Introduction 7

1 Scope 9

2 Normative references 9

3 Terms and definitions 10

4 General requirements 17

4.1 Symbols to be adopted in the future 17

4.2 How to use 17

4.3 Other symbols 18

5 Symbols 18

Appendix A (Informative) Guidelines and examples for using symbols, including multiple symbols 41

Appendix B (Informative) Use of general prohibition symbols and negative symbols 48

References 49

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 1: General requirements;

- 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 5.1.1; 5.1.1 of the 2016 edition);

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);

g) CHANGE the requirements of symbol 5.1.3 in Table 1, deleting the note, adding the usage restrictions (see 5.1.3; 5.1.3 of the 2016 edition);

h) CHANGE the title "lot code" of symbol 5.1.5 in Table 1 into "lot number" (see 5.1.5; 5.1.5 of the 2016 edition);

i) CHANGE the title "serial number" of symbol 5.1.7 in Table 1 into "serial No." (see 5.1.7; 5.1.7 of the 2016 edition);

j) CHANGE the title "non-aseptic" in symbol 5.2.7 in Table 1 into "non-sterile" (see 5.2.7; 5.2.7 in the 2016 edition);

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);

l) CHANGE the title "sterile liquid path" in symbol 5.2.9 in Table 1 into "sterile fluid path" (see 5.2.9; 5.2.9 in the 2016 edition);

m) CHANGE the title of symbol 5.3.3 in Table 1 "Avoid heat and radiation" into "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);

p) CHANGE the description, requirements, usage restrictions of the title in symbol 5.4.4 "Warning" in Table 1, deleting the note (see 5.4.4; 5.4.4 of the 2016 edition);

q) CHANGE the title "sampling location" of symbol 5.6.1 in Table 1 into "sample location" (see 5.6.2; 5.6.2 of the 2016 edition);

r) CHANGE the title "liquid path" of symbol 5.6.2 in Table 1 into "fluid path" (see 5.6.2; 5.6.2 of the 2016 edition);

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 consistency with GB/T 42061-2022;

- DELETE the term "medical device" (see 3.12 of ISO 15223-1:2021), because the "medical device" is defined in medical device regulations and standards, so it is not repeated in this document;

- CHANGE the expression of information about EU regulations in the full text, to comply with China's regulatory requirements.

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).

Drafting organizations of this document: Beijing Guoyi Huaguang Certification Co., Ltd., China Institute for Food and Drug Control, Shenzhen Mindray Biomedical Electronics Co., Ltd., Beijing Wandong Medical Technology Co., Ltd., Shandong Weigao Group Medical Polymer Products Co., Ltd., Shanghai MicroPort Medical Devices (Group) Co., Ltd., Shandong Provincial Food and Drug Evaluation and Inspection Center, Shandong Ande Medical Supplies Co., Ltd., DuPont (China) R&D Management Co., Ltd., Fresenius Kabi (China) Investment Co., Ltd.

The main drafters of this document: Wang Meiying, Wang Tingting, Zheng Jia, Zhang Boxing, Xu Qiang, Liu Lina, Li Ran, Sun Haipeng, Liang Wanjie, Qian Jun, Hong Mei, Chang Jia, Wu Juan, Liu Rongmin, Li Xin, Shao Yubo, Li Zhaohui.

This standard replaces the standard previously issued as follows:

- It was first released in 2003 as YY 0466-2003;

- It was revised for the first time into a sub-part standard in 2009; this document corresponds to YY/T 0466.1-2009;

- It was revised for the second time in 2016;