



PHARMACEUTICAL INDUSTRY STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0466.2-2015 / ISO 15223-2:2010

Partly replacing YY 0466-2003

**Medical devices - Symbols to be used with medical device
labels, labelling, and information to be supplied –**

Part 2: Symbol development, selection and validation

医疗器械 用于医疗器械标签、标记和提供信息的符号

第 2 部分：符号的制订、选择和确认

(ISO 15223-2:2010, IDT)

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Table of Contents

Foreword.....	4
Introduction.....	6
1 Scope	8
2 Normative references	8
3 Terms and definitions	9
4 Principles for identification and development of new symbols	11
4.1 Identifying the need for a symbol	11
4.2 Symbols with horizontal applications	11
4.3 Symbols for use within a restricted range of device types	11
5 Process for selecting and validating symbols for inclusion in ISO 15223-1	11
6 Classification of risk	17
7 Concept development.....	18
7.1 Existence of other symbols.....	18
7.2 Symbol design	18
8 Evaluation.....	19
8.1 Testing early symbol concepts	19
8.2 Comprehension testing	19
8.3 Memory testing.....	20
8.4 Usability testing	20
9 Acceptance criteria.....	21

9.1 General.....	21
9.2 Symbols with no to low safety relevance.....	21
9.3 Symbols with moderate to high safety relevance	22
Annex A (normative) Information to be provided during the symbol development process for adoption of a symbol into ISO 15223-1	23
Annex B (normative) ISO/TC 145/SC 3 proposal for graphical symbols	24
Annex C (normative) IEC/SC 3C proposal for graphical symbol form.....	27
Bibliography.....	29

Foreword

YY/T 0466 consists of the following 2 parts, under the general title “Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied”:

- Part 1: General requirements;
- Part 2: Symbol development, selection and validation.

This Part is Part 2 of YY/T 0466.

This Part is drafted according to the rules given in GB/T 1.1-2009.

This Part, together with published Part 1 YY/T 0466.1-2009 “Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements”, replaces YY 0466-2003. Compared with YY 0466-2003, the main technical changes are as follows:

- YY 0466-2003 is divided into two parts after revision. Part 1 defines the requirements for the development and use of information symbols for the safety and effective use of medical devices. It also lists the symbols that meet the requirements of Part 1;
- This Part specifies the process for the development, selection and validation of candidate symbols proposed for inclusion in Part 1. The aim is to ensure that the symbols contained in Part 1 are easily understood by the target group.

This Part uses the translation method to equivalently adopt ISO 15223-2:2010 “Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 2: Symbol development, selection and validation”.

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This Part is proposed by State Food and Drug Administration.

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This Part of YY/T 0466 partly replaces YY 0466-2003.

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