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**PROFESSIONAL STANDARD OF THE PEOPLE'S  
REPUBLIC OF CHINA**

# **中华人民共和国医药行业标准**

YY/T 0466.1-2009/ISO 15223-1: 2007

Partial Replace YY 0466-2003

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**Medical devices—Symbols to be used with medical  
device labels, labelling and information to be supplied  
—Part 1: General requirements**

**医疗器械 用于医疗器械标签、标记和提供信息的符号**

**第 1 部分：通用要求**

(ISO 15223-1: 2007, IDT)

**Issued on November 25, 2009**

**Implemented on December 01, 2010**

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**Issued by SFDA (State Food and Drug Administration)**

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## Foreword

YY/T 0466 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied* consist of following two parts:

- Part 1: General requirements;
- Part 2: Preparation, selection and confirmation of symbol.

This is Part 1 of YY/T 0466.

This Part is identical to ISO 15223-1: 2007 *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements* (English version)

This Part and Part II to be drafted will replace YY 0466-2003. Comparison with YY 0466-2003, main changes are as follows:

- For safety and efficient use of medical devices in YY 0466-2003, it specifies the symbol for important information to user and other personnel. The revised edition of this Part defines formulation and use requirements for safety of medical device and efficient information symbol, also listing the symbol to meet the requirements of this Part.
- Part II is preparation, selection and confirmation process for symbol in Part 1, it aims to ensure the symbol which easy to understand in Part 1.

Annex A and D of this Standard are informative annex, Annex B and C of this Standard are normative annex.

This Standard is proposed by Medical Device Department of SFDA (State Food and Drug Administration).

This Part is under the jurisdiction of National Technical Committee 221 on Biological Evaluation on Medical Device of Standardization Administration of China.

The drafting organizations are National Technical Committee on Quality Management and

General Requirements for Medical Device of Standardization Administration of China and Beijing Hua Guang Certification of Medical Devices Co., Ltd.

The chief drafting staff of this Part includes Wu Junhua, Chen Zhigang, Mi Lanying, Qin Shuhua and Li Huimin.

This Part replaces YY 0466-2003.

## Introduction

YY/T 0466 addresses symbols that may be used to convey certain items of information that are considered by regulatory authorities to be essential for the safe and proper use of medical devices. As such, the items are required to appear with the device in most regulatory domains. The information may be required on the device itself, as part of the label, or provided with the device. Many countries require that their own language be used to display textual information with medical devices. This raises problems to device manufacturers and users.

Manufacturers seek to take costs out of labelling by reducing or rationalizing variants. This results in a major problem of translation, design and logistics when multiple languages are included on a single label or piece of documentation. Users of medical devices, labelled in a number of different languages, can experience confusion and delay in locating the appropriate language. YY/T 0466 proposes solutions to these problems through the use of internationally recognized symbols with precisely defined meanings.

While compiling symbols to present in YY/T 0466, ISO/TC 210 came to recognise the need for systematic methodology for the development and presentation of symbols proposed for adoption. This will be the subject of a new International Standard to be developed as YY/T 0466-2 on development, selection and validation.

This part of YY/T 0466 is primarily intended to be used by manufacturers of medical devices, who market identical products in countries having different language requirements for medical device labelling. This part of YY/T 0466 may also be of assistance to:

- distributors of medical devices or other representatives of manufacturers;
- health care providers responsible for training as well as those being trained;
- those responsible for post market vigilance;
- health care regulatory authorities, testing organizations, certification bodies and other organizations responsible for implementing regulations affecting medical devices and

having responsibility for post market surveillance.

- consumers or end users of medical devices who draw their supplies from a number of sources and may have varied language capabilities.

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

## **—Part 1: General requirements**

### **1 Scope**

This part of YY/T 0466 identifies requirements for the development and use of symbols that may be used to convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this part of YY/T 0466.

This part of YY/T 0466 is limited to symbols applicable to a broad spectrum of devices that may be marketed globally. These symbols may be used on the device itself or its package or in the associated documentation.

### **2 Normative References**

The articles contained in the following documents have become this Part of YY/T 0466 when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard.

GB/T 7408 Data elements and interchange formats — Information interchange — Representation of dates and times (ISO 8601, IDT)

GB/T 23371.3 Basic principles for graphical symbols for use on electrical equipment - Part 3: Guidelines for the application of graphical symbols (IEC 80416-3, IDT)

IEC 80416-1:2001, Basic principles for graphical symbols for use on equipment — Part 1: Creation of symbol originals

ISO 80416-2, Basic principles for graphical symbols for use on equipment — Part 2: Form and use of arrows

ISO 80416-4, Basic principles for graphical symbols for use on equipment — Part 4:

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