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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0466.2-2015

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

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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 2: Symbol development, selection and validation.

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”.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing organizations of this document shall not be held responsible for identifying any or all such patent rights.

This Part is proposed by State Food and Drug Administration.

This Part is under the jurisdiction of National Technical Committee on Medical Device Quality Management and General Requirements of Standardization Administration of China (SAC/TC 221).

Drafting organization of this Part: Beijing Guo Guang Certification of Medical Devices Co., Ltd.

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Introduction

ISO 15223 addresses symbols that can be used to convey information that is essential for the safe and proper use of medical devices. As such, in most regulatory domains the symbols are required to be presented with the device. The information can be required to be presented on the device itself, as part of the label or provided with the device.

Many countries require that their own language be used to present textual information with medical devices. This presents problems to device manufacturers and users. Faced with the requirement to produce labelling in a number of different languages, manufacturers might have to increase the size of the package or label, thus potentially increasing packaging waste, or compressing the information, thus compromising legibility. Users presented with devices labelled in a number of different languages can experience confusion and delay in locating the needed information in an appropriate language. ISO 15223-1 proposes solutions to these problems through the use of internationally recognized symbols, with precisely defined meanings, that are independent of language.

While compiling the symbols presented in ISO 15223-1:2007, it was recognised that a systematic methodology for the development and presentation of symbols was needed. ISO/TC 210 began by formulating a “best practices” document, Guide to the development and registration of symbols for use in the labelling of medical devices.

When this guide was circulated to interested parties, a number of regulatory authorities were of the opinion that they would have greater confidence in the use of symbols to replace text if the best practices set out in the Guide were expressed as normative requirements in a standards document. Some of the best practices for symbols development and usage have been translated into normative requirements in ISO 15223.

Much of the information required on a medical device itself, as part of the label, or provided with the device constitutes information for safety within an integrated approach to risk management. As with any risk control measure, the manufacturer needs to verify the effectiveness of the information for safety before it can be accepted. The use of standardized symbols agreed by consensus on an international basis can address the confusion that users can experience when presented with labelling in a number of different languages. However, the proliferation of symbols without control and harmonization is undesirable and detracts from the effectiveness of using symbols to convey information for safety. In addition, some users and regulatory authorities have concerns that the unrestricted use of symbols without validation can represent a hazard.

This Part includes methods for validating those candidate symbols being proposed for inclusion in ISO 15223-1. It can also be used by manufacturers and regulators for validating symbols for use with medical devices, where suitable symbols are not standardized.

This Part has been prepared to influence the quality of symbols developed for use in labelling by establishing a process that addresses the need to ensure quality of symbols accepted in ISO 15223-1 by:

providing guidance on development of symbols;

carrying out testing to make sure that the candidate symbol is suitable for adoption and use.

When the processes detailed in this Part have been carried out, the probability of misinterpretation of symbols accepted in ISO 15223-1 is reduced.

validation of symbols in ISO 15223-1. Proposals of the symbols to be included in YY/T 0466.1 shall be submitted to the International Organization for Standardization/Technical Committee on Medical Device Quality Management and General Requirements/Symbols and Nomenclature of Medical Devices (ISO/TC 210/WG 3) via the SAC/TC221 Secretariat, any person or group may propose a symbol.

1 Scope

This Part of YY/T 0466 specifies a process for developing, selecting and validating symbols for inclusion in ISO 15223-1.

The purpose of this Part is to ensure that symbols included in ISO 15223-1 are readily understood by the target group.

If the symbol validation process detailed in this Part has been complied with, then the residual risks, as defined in ISO 14971 and IEC 62366, associated with the usability of a medical device symbol are presumed to be acceptable, unless there is objective evidence to the contrary.

This Part is not restricted to symbols intended to meet regulatory requirements or specified in regulatory guidelines on labelling.

2 Normative references

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

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 (ISO 15223- 1:2007, IDT) ISO 9186-1:2007 Graphical symbols - Test methods - Part 1: Methods for testing comprehensibility IEC 80416-1:2008 Basic principles for graphical symbols for use on equipment - Part 1: Creation of graphical symbols for registration ISO 80416-2 Basic principles for graphical symbols for use on equipment - Part 2: Form and use of arrows

3 Terms and definitions

Procedure for ranking candidate symbols according to their considered appropriateness for representing a particular meaning.

Procedure for comparing the strength of an association between a candidate symbol and several possible meanings.