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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 29791.1-2013

In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 1: Terms, definitions and general requirements

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Foreword

GB/T 29791 "in vitro diagnostic medical devices - Information supplied by the manufacturer (labeling)" is divided into five parts.

--- Part 1. Terms, definitions and general requirements;

--- Part 2. In vitro diagnostic reagents for professional use;

--- Part 3. In vitro diagnostic instruments for professional use;

--- Part 4. In vitro diagnostic reagents for self;

--- Part 5. In vitro diagnostic instruments for self.

This section GB/T 29791 Part 1.

This section drafted in accordance with GB/T 1.1-2009 given rules.

This section uses the translation method identical with ISO 18113-1.2009 "in vitro diagnostic medical device manufacturers to provide information (labeling)

Part 1. Terms, definitions and general requirements. "

Consistency correspondence between this part of international documents and normative references of our files are as follows.

--- GB 3100-1993 International System of Units and Its Application (eqv ISO 1000.1992)

--- YY/T 0287-2003 medical device quality management system for regulatory requirements (ISO 13485.2003, IDT)

--- YY/T 0316-2008 medical device risk management to medical devices applications (ISO 14971.2007, IDT)

Symbols - Part 1 --- YY/T 0466.1-2009 medical equipment used with medical device labels, labeling and information provided. pass

With requirements (ISO 15223-1.2007, IDT)

Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of

these patents.

This part is proposed by the State Food and Drug Administration.

This part of the National Medical clinical testing laboratory and in-vitro diagnostic systems for Standardization Technical Committee (SAC/TC136) centralized.

This section is drafted. Beijing Medical Device Testing.

Introduction

Vitro diagnostic (IVD) medical device manufacturers can provide the user with the safe use of the instrument and the achievement of its expected performance information. Tradition

On the information provided to the label, package inserts and user manuals form. The form and level of detail generally depends on the intended use and the specific country

Global Harmonization Task Force (GHTF) encourages global regulatory system for medical devices to converge with the aim of promoting trade and at the same time guarantee

Members to stay involved in the form of regulations, the powers of public health protection. Consistent with worldwide labeling requirements may give manufacturers, users, patients

And regulatory authorities to bring significant benefits. Eliminate differences between jurisdictions and regulations can reduce the time required to obtain regulatory approval, which can make patients more

Ease of access to new technologies and treatments, see reference [36]. This section provides coordination vitro diagnostic medical devices on the basis of labeling requirements.

GHTF has established guidelines for medical device labeling, see Ref. [36]. These principles have been integrated into

GB/T 29791/ISO 18113 series of standards. Special attention is, GHTF recommends that the content of the labels and instructions for use, and format text

Style country-specific requirements should be kept to a minimum level, and eliminate these differences when mature over a period of time to be opportunities.

This section contains the vocabulary and terms to develop in vitro diagnostic medical devices labeled needed. If the international definition of the key concepts of reach

Consensus, will largely promote the in vitro diagnostic medical devices marked consistency. Although the goal is marked in vitro diagnostic medical devices in use

The standardization of terminology in the extent possible, but also recognizes that currently are considered national and regional medical laboratories, medical staff, patients and regulatory authorities

With usage must be respected.

In some countries, in vitro diagnostic medical devices timeliness and affordability barriers still request for information to appear in multiple languages. in

Any practicable, as long as the user will not reduce the terms of understanding the impact of the safe use of equipment, GHTF encourages the use of standards

Oriented, internationally recognized symbols. This standard is consistent with the target symbol GHTF support.

GHTF also encourages manufacturers to adopt the most appropriate way to release information. Until now most of the information that came to be in vitro diagnostic medical

Instruments to provide printed material. Modern technology makes use of technical information and instructions may be provided with a more efficient way. Digital information can be compiled

Code on magnetic or optical media, displayed on the screen of the device that contains, or even transfer when using the Internet. Such advances offer the user

More timely access to critical information may be provided, such as changes in performance and enables manufacturers to more efficient distribution of information.

GB/T 29791 series of standards provides for the in vitro diagnostic medical device manufacturers to provide information about the requirements of standards published in five parts,

It makes it the most appropriate way to focus on the specific needs of professional users and non-professional users. Further, since the manufacturer is an in vitro diagnostic

Off reagents and equipment to provide different types of information, their requirements described in a separate section of this series of standards.

This section is not intended to be used alone, it contains the term applies to GB/T 29791 all parts of the definitions and general requirements. Also in this

Appendixes A description is given in vitro diagnostic medical device performance characteristics of terms, definitions guidelines. This part of the information in GB/T 29791 Other

Section will not be repeated, so this part of the GB/T 29791.2, GB/T 29791.3, GB/T 29791.4, GB/T 29791.5 application is

Indispensable.

GB/T 29791.2 provisions of the labels and instructions for professional use in vitro diagnostic reagents, calibrators and control materials provided by request.

GB/T 29791.3 provides for labeling and instructions for use in vitro diagnostic instruments

for professional use provided requirements. GB/T 29791.4 provides for self-test

Using an in vitro diagnostic reagents, calibrators and control materials provided by the labels and instructions for use requirements. GB/T 29791.5 provides for self-test use in vitro

Instructions for use of diagnostic requirements provided by the instrument.

GB/T 29791 Part 1, Part 2, Part 3 is the standard use of medical laboratories and other specialized needs.

GB/T 29791 Part 1, Part 4, Part 5 is the standard for self-vitro diagnostic medical devices needed. However, that manufacturing

Suppliers often provided by the instrument and a dedicated reagent system composed of these standards allow the most appropriate form of flexibility to raise user expectations

For the necessary information. For example, the integration of in vitro diagnostic medical devices in a single system manual.

In vitro diagnostic medical device manufacturers to provide information

(Flag) - Part 1. Terms, definitions and general requirements

1 Scope

This section GB/T 29791 for information on the definition of the concept of in vitro diagnostic medical devices supplied by the manufacturer to establish the general principles and provisions

basic requirements.

Language belongs to the scope of national laws and regulations, we will not be discussed in this section.

This section does not apply to.

a) Performance evaluation of in vitro diagnostic medical devices (such as for research use only);

b) instrument mark;

c) safety data sheet.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein

Member. For undated references, the latest edition (including any amendments) applies to this document.