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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 29791.2-2013

In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 2: In vitro diagnostic reagents for professional use

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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 2.

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

This section uses the translation method identical with ISO 18113-2.2009 "in vitro diagnostic medical device manufacturers to provide information (labeling)

Part 2. In vitro diagnostic reagents for professional use. "

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

--- GB/T 7408-2005 data elements and interchange formats - Information interchange dates and times (ISO 8601.1998,

IDT)

--- YY/T 0316-2008 medical device risk management to medical devices applications (ISO 14971.2008, 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

Professional in vitro diagnostic use (IVD) reagents supplied by the manufacturer to the user is able to use safety equipment and achieve its expected performance information. its

The form and level of detail as the intended use and the country-specific regulations vary.

Global Harmonization Task Force (GHTF) encourages global regulatory system for medical devices to converge. Eliminate differences between jurisdictions and regulations can be

So patients earlier access to new technologies and treatments, see reference [9]. This section provides professional coordination with the labeling requirements of the IVD reagent

basis.

This section is concerned only with the IVD reagents for professional use is expected, calibrators and control materials information provided. This section is intended and

GB/T 29791.1 used in combination, the standard contains the definition of common requirements for the information provided by the manufacturer and marked general concepts.

This section based on EN375.2001 [5]. In order to comply with ISO /IEC Guide Part 2 [4], the text has been modified, but the requirements, including

Enclosed in GB/T 29791.1 requirements substantially equivalent to the original harmonized European standards. This section is intended to support all GHTF participating countries,

And basic labeling requirements in other countries are implementing or planning to implement IVD medical device labeling regulations.

As expected for IVD reagent systems and equipment supplied by the same manufacturer used together, calibrators and (or) controlled substances, present

Part is also expected to be used with the GB/T 29791.1 and GB/T 29791.3.

In vitro diagnostic medical devices

Information supplied by the manufacturer (labeling)

Part 2. In vitro diagnostic reagents for professional use

1 Scope

This section GB/T 29791 specifies the professional use in vitro diagnostics (IVD) reagent manufacturer's information requirements.

This section also applies to professional calibration was expected and in vitro diagnostic medical devices for use with controlled substance information provided by the manufacturer.

This section also applies to IVD Annex.

This section applies to outer and inner packaging label and instructions for use.

This section does not apply to.

a) in vitro diagnostic instruments or equipment;

b) self-test in vitro diagnostic reagents.

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.

ISO 8601 Data elements and interchange formats - Information interchange the date and time notation (Dataelementsandinterchange

formats-Informationinterchange-Representationofdatesandtimes)

ISO 14971 Medical Device Risk Management for Medical Device Applications (Medicaldevices-Applicationofriskman-

agementtomedicaldevices)

Symbols - Part 1 ISO 15223-1 for medical equipment with medical device labels, labeling and information. General requirements

(Medicaldevices-Symbolstobeusedwithmedicaldevicelabels, labelingandinformationtobesup-

plied-Part 1. Generalrequirements)

ISO 18113-1 In vitro diagnostic medical device manufacturers to provide information (labeling) - Part 1. Terms, definitions and general requirements

[Invitrodiagnosticmedicaldevices-Informationsuppliedbythemanufacturer (labeling) -Part 1.

Terms, definitionsandgeneralrequirements]

EN980 medical devices used in the labeling symbol (Symbolsforuseinthelabelingofmedicaldevices)

3 Terms and Definitions

Terms and definitions defined in ISO 18113-1 apply to this document.

4.1 Basic requirements

ISO 18113-1 apply.