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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 29791.5-2013

In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 5: In vitro diagnostic instruments for self-testing

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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 5.

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

This section uses the translation method identical with ISO 18113-5.2009 "in vitro diagnostic medical device manufacturers to provide information (labeling) Article

Part 5. In vitro diagnostic instruments for self. "

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

--- 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)

--- GB 4793.1-2007 measurement, control and laboratory safety requirements for electrical equipment - Part 1. General requirements

(IEC 61010-1.2001, IDT)

--- YY0648-2008 measurement, control and laboratory safety requirements for electrical equipment - Part 2-101. In vitro diagnostic

(IVD) requirements for medical equipment (IEC 61010-2-101.2002, 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

Self-test (IVD) equipment manufacturers to provide the user can safely use and achieve its expected performance of devices used in vitro diagnostic information. Charge

Minute instructions for the use of safe and proper operation IVD instrument is required. The form and level of detail as the intended use and the country-specific

Regulatory changes.

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 [7]. This standard provides coordination IVD instruments for self labeling requirements

basis.

This section is concerned only with IVD instruments and equipment to the expected use of the self-test information provided. This section is intended and GB/T 29791.1 United

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 EN592 [5]. In order to comply with ISO /IEC Guide Part 2 [4], the text has been modified, but the requirements, including the

GB/T 29791.1 of the requirements, substantially equivalent to the initial harmonized European standards. This section is intended to support all GHTF participating countries, as well as

Other embodiments or planning to implement basic labeling requirements IVD medical device labeling regulations of the State.

For IVD instruments and reagents is expected as the system provided by the same manufacturer for use with this section and is also expected to

GB/T 29791.1 and GB/T 29791.4 used together.

In vitro diagnostic medical devices

Information supplied by the manufacturer (labeling)

Part 5. In vitro diagnostic instruments for self

1 Scope

This section GB/T 29791 provides for self-test use in vitro diagnostics (IVD) equipment manufacturers to provide the information requested.

This section also applies to equipment and devices for self expectations and in vitro diagnostic medical instruments used in conjunction.

This section also applies to IVD Annex.

This section does not apply to.

a) equipment maintenance or repair instructions;

b) in vitro diagnostic reagents, including calibrators and control of controlled substances for the agent;

c) in vitro diagnostic instruments for professional use.

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 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)

IEC 61010-1 measurement, control and laboratory safety requirements for electrical equipment - Part 1. General requirements (Safetyrequire-

mentsforelectricalequipmentformeasurement, controlandlaboratoryuse-Part 1. Generalrequire-

ments)

IEC 61010-2-101 measurement, control and laboratory safety requirements for electrical equipment - Part 2-101. In vitro diagnostic (IVD) Medical

With special equipment requirements (Safetyrequirementsforelectricalequipmentformeasurement, controlandlabora-

toryuse-Part 2-101. Particularrequirementsforinvitrodiagnostic (IVD) medicalequipment)

IEC 61326-2-6 measurement, control and laboratory use EMC requirements for electrical equipment Part 2-6. Particular requirements for in vitro

Diagnostic (IVD) medical equipment (Electricalequipmentformeasurement, controlandlaboratoryuse-EMCre-

quirements-Part 2-6. Particularrequirements-Invitrodiagnostic (IVD) medicalequipment)

IEC 62366 Medical Devices to use engineering applications (Medicaldevices-Applicationof on medical devices

usabilityengineeringtomedicaldevices)

EN980 medical devices used in the labeling symbol (Symbolsforuseinthelabelingofmedicaldevices)