NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 29791.3-2013

In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 3: In vitro diagnostic instruments for professional use

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Foreword

GB/T 29791 `` Information provided by manufacturers of in vitro diagnostic medical devices (labeling) '' is divided into 5 parts.

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

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

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

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

--- Part 5. Self-test in vitro diagnostic equipment.

This part is the third part of GB/T 29791.

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

This section uses the translation method equivalent to ISO 18113-3..2009 "Information provided by manufacturers of in vitro diagnostic medical devices (labeling)

Part 3. In vitro diagnostic equipment for professional use.

The Chinese documents that have a consistent correspondence with the international documents referenced normatively in this section are as follows.

--- YY/T 0316-2008 Application of medical device risk management to medical devices (ISO 14971..2008, IDT)

--- YY/T 0466.1-2009 Medical devices-Symbols used for labeling, marking and providing information of medical devices-Part 1. General

Requirements (ISO 15223-1..2007, IDT)

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

(IEC 61010-1..2001, IDT)

--- YY0648-2008 Safety requirements for electrical equipment for measurement, control and laboratory use-Part 2-101. In vitro diagnostics

(IVD) Specific requirements for medical equipment (IEC 61010-2-101..2002, IDT)

Please note that some elements of this document may involve patents. The issuer of this document is not responsible for identifying these patents.

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

This section is under the jurisdiction of the National Medical Clinical Laboratory Laboratory and the Standardization Technical Committee for In vitro Diagnostic Systems (SAC/TC136).

This section was drafted. Beijing Medical Device Inspection Institute.

introduction

Manufacturers of professional in vitro diagnostic (IVD) equipment provide information to users that enables them to safely use and achieve the expected performance of their devices. its

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

The Global Harmonization Task Force (GHTF) encourages a global consensus on medical device regulatory systems. Eliminating discrepancies between jurisdictions

Make patients get new technology and treatment earlier, see reference [5]. This section provides guidelines for harmonizing the marking requirements of professional IVD instruments.

basis.

This section focuses only on the information provided for IVD instruments and equipment intended for professional use. This section aims to align with GB/T 29791.1

For joint use, this section contains the general requirements for the information provided by the manufacturer and the definition of the universal labeling concept.

This section is based on EN591 [3]. In order to comply with the ISO /IEC Guide Part 2 [2], the text has been modified, but the requirements, including

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

Basic labeling requirements in other countries that implement or plan to implement IVD medical device labeling requirements.

For IVD instruments intended to be used as a system with reagents provided by the same manufacturer, this section also

GB/T 29791.1 and GB/T 29791.2 are used together.

Information provided by IVD medical device manufacturers (labeling)

Part 3. In vitro diagnostic equipment for professional use

1 Scope

This part of GB/T 29791 specifies the requirements for information provided by professional in vitro diagnostic (IVD) instrument manufacturers.

This section also applies to devices and equipment intended for use with professional in vitro diagnostic medical devices.

This section also applies to IVD attachments.

This section does not apply to.

a) instructions for servicing or repairing the instrument;

b) in vitro diagnostic reagents, including calibrators and control substances used to control the reagents;

c) In vitro diagnostic equipment for self-test.

2 Normative references

The following documents are essential for the application of this document. For dated references, only the dated version applies to this article

Pieces. For undated references, the latest version (including all amendments) applies to

this document.

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

agementtomedicaldevices)

ISO 15223-1 Medical devices. Symbols for labelling, labelling, and providing information in medical devices. Part 1. General requirements

(Medicaldevices-Symbolstobeusedwithmedicaldevicelabels, labelingandinformationtobesup-

plied-Part 1. Generalrequirements)

Information from ISO 18113-1 manufacturers of in vitro diagnostic medical devices (labelling) Part 1. Terms, definitions and general requirements

[Invitrodiagnosticmedicaldevices-Informationsuppliedbythemanufacturer (labeling) -Part 1.

Terms, definitionsandgeneralrequirements]

IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 1. General requirements

mentsforelectricalequipmentformeasurement, controlandlaboratoryuse-Part 1. Generalrequire-

ments)

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

Special requirements for equipment used [Safetyrequirementsforelectricalequipmentformeasurement, controlandlabora-

toryuse-Part 2-101. Particular requirements for invitrodiagnostic (IVD) medicalequipment]

IEC 61326-2-6 Requirements for electromagnetic compatibility of electrical equipment for measurement, control and laboratory use-Part 2-6. Special requirements

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

quirements-Part 2-6. Particular requirements-Invitrodiagnostic (IVD) medicalequipment]

IEC 62366 Medical Device-Application of Medical Devices

usabilityengineeringtomedicaldevices)

EN980 Symbols for use in the labeling of medical devices