SLOVENSKI STANDARD
oSIST prEN ISO 18113-3:2021

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In vitro diagnostični preskusni sistemi - Informacije proizvajalca (označevanje) - 3. del: Diagnostični instrumenti in vitro za poklicno uporabo (ISO/DIS 18113-3:2021)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO/DIS 18113-3:2021)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 3: Geräte für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal (ISO/DIS 18113-3:2021)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 3: Instruments de diagnostic in vitro à usage professionnel (ISO/DIS 18113-3:2021)

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ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

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In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 3:
In vitro diagnostic instruments for professional use

Dispositifs médicaux de diagnostic in vitro — Informations fournies par le fabricant (étiquetage) — Partie 3: Instruments de diagnostic in vitro à usage professionnel

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 18113-3:2009), which has been technically revised.

The main changes compared to the previous edition are as follows:

— Updated text to reflect changes in regulations and provide examples for clarity

— Added Information pertaining to UDI (Unique Device Identifier/Identification)

— Updated bibliography

In this document, the following verbal forms are used: — "shall" indicates a requirement; — "should" indicates a recommendation; — "may" indicates a permission; — "can" indicates a possibility or a capability. Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

A list of all parts in the ISO 18113 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Manufacturers of in vitro diagnostic (IVD) instruments for professional use supply users with information to enable the safe use and expected performance of their devices according to the intended use. The type and level of detail varies according to the intended uses and country-specific regulations.

The International Medical Device Regulators Forum (IMDRF) encourages convergence of the evolution of regulatory systems for medical devices at the global level. Eliminating differences among regulatory jurisdictions could allow patients earlier access to new technologies and treatments. This document provides a basis for harmonization of labelling requirements for IVD instruments for professional use.

This document is concerned solely with information supplied with IVD instruments and equipment intended for professional use. It is intended to be used in conjunction with ISO 18113-1, which contains the general requirements for information supplied by the manufacturer and definitions of general labelling concepts.

This document is intended to support the essential labelling requirements of all the IMDRF [6] partners, as well as other countries that have or plan to enact labelling regulations for IVD medical devices.

For IVD instruments for professional use that are intended to be used as a system with reagents provided by the same manufacturer, this document is also intended to be used together with ISO 18113-1 and ISO 18113-2.

In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 3: In vitro diagnostic instruments for professional use

1 Scope

This document specifies requirements for information supplied by the manufacturer of IVD instruments intended for professional use.

This document also applies to apparatus and equipment intended to be used with IVD instruments for professional use.

This document can also be applied to accessories.

This document does not apply to:

a) instructions for instrument servicing or repair;

b) IVD reagents, including calibrators and control materials for use in control of the reagent;

c) IVD instruments for self-testing.

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.

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 18113-1, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements*

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

IEC 61010-2-101, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment*

IEC 61326-2-6, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18113-1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 Essential requirements

The requirements of ISO 18113-1 apply.

5 Labels and marking

5.1 General

The requirements of IEC 61010-1, IEC 61010-2-101 and IEC 61326-2-6 concerning labels and marking apply.

For the use of symbols, the requirements of ISO 15223-1 apply.

The labelling shall not contain any language regarding the manufacturer's liability in the case of damage or injury resulting from any use or malfunction of the device that contradicts the laws or regulations in the jurisdiction of use.

The labelling shall not contain any disclaimers related to the safety and performance of the device for its intended purpose that are incompatible with the laws or regulations in the jurisdiction of use, or the obligations of the manufacturer to design and manufacture a product that is safe and performs as intended throughout its expected lifetime.

5.2 Identification of the IVD instrument

5.2.1 IVD instrument name

The name or trade name of the IVD instrument shall be given.

When the name does not uniquely identify the IVD instrument, an additional means of identification shall also be given.

EXAMPLES Catalogue number, commodity number.

5.2.2 Serial number

A unique serial number shall be given for IVD instruments.

All instruments covered by the IEC 61010 series require serial numbers.

Where serial numbers are not practical for apparatus, equipment or accessories intended to be used with IVD instruments, a batch code may be used instead.

EXAMPLE A primary sample receptacle would be assigned a batch code.

5.2.3 In vitro diagnostic use

The IVD use of the instrument shall be indicated when required by regulation.

EXAMPLES The words "for in vitro diagnostic use" or graphical symbol: "in vitro diagnostic medical device".

NOTE In some countries, authorities having jurisdiction can set local requirements for the content of the intended use statement. For example, in the United States, an indication is given that the device is intended for IVD use.

