SLOVENSKI STANDARD
oSIST prEN ISO 18113-2:2021

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In vitro diagnostični preskusni sistemi - Informacije proizvajalca (označevanje) - 2. del: Diagnostični reagenti in vitro za poklicno uporabo (ISO/DIS 18113-2:2021)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO/DIS 18113-2:2021)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 2: In-vitro-diagnostische Reagenzien für den Gebrauch durch Fachpersonal (ISO/DIS 18113-2:2021)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 2: Réactifs de diagnostic in vitro à usage professionnel (ISO/DIS 18113-2:2021)

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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 2:
In vitro diagnostic reagents for professional use

Partie 2: Réactifs 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 18113:2009), which has been technically revised.

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

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

— Updated with examples to reference European Union and other regulations

— Added additional detail for clarification

— Updated the 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) reagents for professional use, supply users with information to enable their safe use and the expected performance of their devices. The type and level of detail varies according to the intended uses and country-specific regulations.

The International Medical Devices Regulatory 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 reagents for professional use.

This document is concerned solely with information supplied with IVD reagents, calibrators and control materials 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 reagents, calibrators and/or control materials that are intended to be used as a system with an instrument provided by the same manufacturer, this document is also intended to be used together with ISO 18113-1 and ISO 18113-3.

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

Part 2: In vitro diagnostic reagents for professional use

1 Scope

This document specifies requirements for information supplied by the manufacturer of IVD reagents, calibrators and controls intended for professional use.

This document can also be applied to accessories.

This document applies to the labels for outer and immediate containers and to the instructions for use.

This document does not apply to:

a) IVD instruments or equipment;

b) IVD reagents for self-testing.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

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*

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 General

4.1 Essential requirements

The requirements of ISO 18113-1 apply.

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

4.2 Identification of kit components

In the case of a kit, each component shall be identified by name, letter, number, symbol, colour, or graphics in the same manner on all labels and in the instructions for use.

NOTE A UDI is not required on the immediate label of kit components unless the component is a device in its own right.

5 Content of the outer container label

5.1 Manufacturer

The name and address of the manufacturer shall be given. The address indicates a single point at which the manufacturer can be contacted, for example, street, number, city, postal code, country. If a full address is not practical, an abbreviated version may be sufficient provided the full address is included in the instructions for use.

If an Authorized Representative is acting on behalf of the manufacturer in the country/jurisdiction, the label shall also contain the address of the Authorized Representative if required by the regulatory authority having jurisdiction.

5.2 Identification of the *in vitro* diagnostic (IVD) reagent

5.2.1 IVD reagent name

The name or trade name of the IVD reagent shall be given. This brand or trade name should allow its differentiation from other products of the same or similar type. When the name does not uniquely identify the IVD reagent, an additional means of identification shall also be given.

EXAMPLES Catalogue number, commodity number

5.2.2 Batch code/lot number

A batch code/lot number, shall be given.

If a kit contains different components bearing different batch codes, the batch code indicated on the outer container shall enable the individual batch code of each component to be traced from the manufacturer's production record.

5.2.3 Unique device identifier/identification (UDI)

If an IVD reagent is subject to unique identification rules by the regulatory authority, the outer label shall include the UDI including the UDI carrier (Automatic Identification Data Carrier 'AIDC' format), and Human Readable Interpretation (HRI).

NOTE 1 The content, format, and size of the UDI is defined by the accredited UDI issuing agency selected.

NOTE 2 When AIDC carriers other than the UDI Carrier are part of the product labelling, the UDI Carrier shall be readily identifiable.

