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

Part 2: In vitro diagnostic reagents for professional use

Dispositifs médicaux de diagnostic in vitro — Informations fournies par le fabricant (étiquetage) —

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 18113-2:2009), which has been technically revised.

The main changes are as follows:

— Added Information pertaining to (unique device identifier-device identifier) UDI;

— Updated with examples to reference European Union and other regulations;

— Added additional detail for clarification;

— Updated the Bibliography.

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 the 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 Regulators Forum (IMDRF) encourages convergence of the evolution of regulatory systems for medical devices at the global level. Eliminating differences among regulatory jurisdictions can 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[8] 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 in vitro diagnostic (IVD) reagents, calibrators and controls intended for professional use.

This document can also be applicable to accessories.

This document is applicable 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 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — 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 terminology 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, e.g. 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, whether the regulatory authority having jurisdiction requires that the label shall also contain the address of the Authorized Representative, should be taken into consideration.

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 (UDI)

It should be taken into consideration that if an IVD reagent is subject to unique identification rules by the regulatory authority, the outer label should provide the UDI including the UDI carrier (Automatic Identification Data Carrier 'AIDC' format), and Human Readable Interpretation (HRI).

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

The UDI shall include both the UDI device identifier (UDI-DI) and the UDI production identifier (UDI-PI); specific exemptions which are provided by regulations should be taken into consideration.

For the IVD reagent, the UDI-PI shall include at least the batch code and the expiry date.

If there also is a manufacturing date on the label for reasons other than batch control purposes, it does not need to be included in the UDI-PI; specific requirements provided by regulations should be taken into consideration.

If there are significant constraints limiting the use of both AIDC and HRI on the label, the AIDC format shall be generally preferred except for environments where HRI is more appropriate to the user.

The UDI carrier should be readable during normal use, storage conditions, and throughout intended life of the IVD reagent. ISO/IEC 15415 should be referred to for bar code specifications and symbol quality criteria.

Local, national or regional regulations can apply.

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

NOTE 2 HRI text is not the same as the text that is already placed on the label and is a legible interpretation of the data characters encoded in the UDI Carrier.

5.3 Contents

The net quantity of contents expressed in terms of mass, volume, volume after reconstitution, numerical or a combination of these or other terms that accurately reflect the contents shall be indicated.

5.4 Intended use/Intended purpose

If the intended use is not indicated by the name of the IVD reagent or an appropriate symbol, then an abbreviated intended use that contains enough detail for the user to identify the device and its use shall be given. A full intended use statement shall be given in the instructions for use.

NOTE In some countries, authorities having jurisdiction can set local requirements for the content of the intended use statement. For example, in the European Union, an indication is given that the device is intended for near-patient testing.

5.5 In vitro diagnostic use

The IVD use of the reagent shall be indicated.

EXAMPLES “For in vitro diagnostic use” or the graphical symbol for “in vitro diagnostic medical device”.

5.6 Storage, transport, and handling conditions

The storage conditions necessary to maintain the stability of the reagents, calibrators and control materials in the unopened state shall be indicated. Use of non-specific temperature or humidity indications that are open to interpretation shall be avoided.

EXAMPLE 1 2 °C to 8 °C or 2…8 °C or graphical symbol; –18 °C or below or ≤ –18 °C or graphical symbol.

Other conditions that affect stability shall be indicated.

EXAMPLE 2 Light, humidity.

Any other conditions that affect the handling, transport or storage of the reagents, calibrators, and control materials shall be specified.

EXAMPLE 3 Fragile.

EXAMPLE 4 Keep vials protected from light.

Other protective measures which users should take to mitigate conditions that can affect stability shall be stated.

5.7 Expiry date

An expiry date based upon the stated storage instructions shall be indicated.

Expiry dates shall be expressed as the year, the month, and, where relevant, the day. The requirements of ISO 8601-1 apply.

EXAMPLES "YYYY-MM-DD" or "YYYY-MM".

If only the year and month are given, the expiry date shall be the last day of the month indicated.

The label of the outer container shall indicate the expiry date of the component having the earliest expiry date, or an earlier date, where appropriate.

5.8 Warnings and precautions

If an IVD reagent is considered hazardous, the outer container label shall include the appropriate hazard pictogram(s). The appropriate signal word, product identifiers, hazard statements and precautionary statements should be included. However, where there is insufficient space, the hazard pictogram shall be given on the outer container label and the other information shall be given in the instructions for use.

EXAMPLES Chemical, radioactive, and biological hazards.

In the case of chemical hazards, if the IVD reagent is not accompanied by instructions for use containing the appropriate risk and safety statements, these statements shall be given on the label of the outer container.

Statements or warning symbols for specific hazards can be required by local, national or regional regulations.

6 Content of the immediate container label

6.1 General provisions

6.1.1 Single container

If the immediate container is the outer container, the requirements specified in Clause 5 apply.

6.1.2 Small label

If the available space on the immediate container label is too small to include all the information listed below, the information about contents (6.4), IVD use (6.5), and storage and handling conditions (6.6) and manufacturer address (6.2) may be abbreviated or eliminated.

Local, national or regional regulations can apply.

6.2 Manufacturer

The manufacturer shall be identified. The name of the manufacturer or an unequivocal trade name or logo is sufficient. For inclusion of the manufacturer address, see 5.1.

6.3 Identification of the IVD reagent

6.3.1 IVD reagent or component name

The name shall ensure proper identification to the user of the IVD reagent or component.

6.3.2 Batch code/lot number

A batch code and where appropriate, a lot number, shall be given.