INTERNATIONAL STANDARD

ISO 18113-4

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

Part 4: *In vitro* diagnostic reagents for self-testing

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

Partie 4: Réactifs de diagnostic in vitro pour auto-tests

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 18113-4 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*

ISO 18113 consists of the following parts, under the general title In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling)*:

— *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-testing*

— *Part 5:* In vitro *diagnostic instruments for self-testing*

Introduction

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

The Global Harmonization Task Force (GHTF) 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. See Reference [9]. This part of ISO 18113 provides a basis for harmonization of labelling requirements for IVD reagents for self-testing.

This part of ISO 18113 is concerned solely with information supplied with IVD reagents, calibrators and control materials intended for self-testing. 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 part of ISO 18113 is based on EN 376:2002[5]. The text has been modified to conform to Part 2 of the ISO/IEC Directives[4], but the requirements, including those in ISO 18113-1, are substantially equivalent to the original European harmonized standard. This part of ISO 18113 is intended to support the essential labelling requirements of all the GHTF partners, as well as other countries that have enacted 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 part of ISO 18113 is also intended to be used together with ISO 18113-1 and ISO 18113-5[3].

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

Part 4: *In vitro* diagnostic reagents for self-testing

1 Scope

This part of ISO 18113 specifies requirements for information supplied by the manufacturer of IVD reagents for self-testing.

This part of ISO 18113 also applies to information supplied by the manufacturer with calibrators and control materials intended for use with IVD medical devices for self-testing.

This part of ISO 18113 can also be applied to accessories.

This part of ISO 18113 applies to the labels for outer and immediate containers and to the instructions for use.

This part of ISO 18113 does not apply to:

a) IVD instruments or equipment,

b) IVD reagents for professional use.

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*

EN 980, *Symbols for use in the labelling of medical devices*

3 Terms and definitions

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

4 General

4.1 Essential requirements

The requirements of ISO 18113-1 apply. For the use of symbols, the requirements of ISO 15223-1 and EN 980 apply.

ISO standards for specific IVD medical devices may also contain requirements for information supplied by the manufacturer.

EXAMPLES ISO 15197[1]; ISO 17593[2].

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.

4.3 Presentation of the instructions for use

4.3.1 The instructions for use shall be written to be easily understood and applied by a lay person, and where appropriate, supplemented with drawings and diagrams.

Some devices may require separate information for the healthcare professional.

4.3.2 The information supplied shall be sufficient to enable a lay person to use the IVD reagent safely and properly, and to understand the IVD examination results.

NOTE Recommendations for developing user instruction manuals for IVD medical devices used in home health care are found in Reference [10].

5 Content of the outer container label

5.1 Manufacturer

The name and address of the manufacturer shall be given.

NOTE In the European Union, the name and address of the manufacturer's “EC Authorized Representative” is required on the outer container label or in the instructions for use, if the legal manufacturer is not located within the EU. See Reference [8].

5.2 Identification of the IVD reagent

5.2.1 IVD reagent name

The name of the IVD reagent shall be given.

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

A batch code 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.

5.3 Contents

The mass, volume and/or the number of examinations shall be indicated.

5.4 Intended use

If the intended use is not indicated by the name of the IVD reagent, then an abbreviated intended use statement shall be given or included in the instructions for use in terminology suitable for a lay person.

EXAMPLE Pregnancy test.

The fact that the IVD reagent is intended for self-testing shall be clearly stated.

5.5 *In vitro* diagnostic use

The *in vitro* diagnostic use of the reagent shall be indicated in terminology suitable for a lay person.

EXAMPLE Only for use outside the body.

5.6 Storage 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.

EXAMPLE 1 2 °C to 8 °C or 2…8 °C or graphical symbol.

–18 °C or below or graphical symbol.

Other conditions that affect stability shall be indicated.

EXAMPLE 2 Light, humidity.

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

EXAMPLE 3 Fragile.

5.7 Expiry date

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

Expiry dates shall be expressed in a format generally familiar to the lay person.

EXAMPLES 2007-05-01, 2007-May-01, May 01, 2007.

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

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

Local, national or regional regulations may apply.