INTERNATIONAL STANDARD

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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 destinés aux autodiagnostics

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 18113-4:2009), which has been technically revised.

The main changes are as follows:

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

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

— 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.

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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 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 can allow patients earlier access to new technologies and treatments. This document provides a basis for the harmonization of labelling requirements for IVD reagents for self-testing.

This document 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 document is intended to support the essential labelling requirements of all the IMDRF [8] 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 document is also intended to be used together with ISO 18113-1 and ISO 18113-5.

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

Part 4: In vitro diagnostic reagents for self-testing

1 Scope

This document specifies requirements for information supplied by the manufacturer of in vitro diagnostic (IVD) reagents, calibrators, and controls intended for self-testing.

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 professional use.

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 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.

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