INTERNATIONAL STANDARD

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

Part 1: Terms, definitions, and general requirements

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

Partie 1: Termes, définitions et exigences générales

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Contents

Page

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 18113-1:2009), which has been technically revised.

The main changes are as follows:

— Updated terms and definitions;

— References to the UDI (Unique Device Identifier/Identification) requirement added;

— Updated Bibliography to align with updates of standards and publications;

— Updated to align with European Union and other regulations;

— Added additional detail for clarification.

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) medical devices supply users with information to enable the safe use and expected performance of their devices. Traditionally, this information has been provided in the form of labels, package inserts and user manuals, where the type and level of detail would depend on 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. The goal is to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means. Consistent worldwide labelling requirements offer significant benefits to manufacturers, users, patients and regulatory authorities. Eliminating differences among regulatory jurisdictions can allow patients earlier access to new technologies and treatments by decreasing the time necessary to gain regulatory compliance. This document provides a basis for harmonization of labelling requirements for IVD medical devices. As per ISO 20417, the ISO 18113 series represents a group standard and, therefore, has precedence with regards to the labelling requirements for IVDs.

The Global Harmonization Task Force (GHTF) now replaced by IMDRF (See Reference [52]) has established guiding principles that apply to the labelling of medical devices and IVDs. These principles have been incorporated into the ISO 18113 series. Of particular note, IMDRF states that country-specific requirements for the content, wording and format of labels and instructions for use should be kept to a minimum and eliminated over time as the opportunities arise.

This document contains a comprehensive list of terms and definitions necessary to develop the labelling for IVD medical devices. Internationally agreed-upon definitions of important concepts promote greater consistency in IVD medical device labelling. While the goal is to standardize the terminology used in IVD medical device labelling to the extent possible, it is also recognized that current national and regional usage by medical laboratories, healthcare providers, patients and regulatory authorities should be taken into consideration

An obstacle to the timely and affordable availability of IVD medical devices in some countries is the requirement for information to appear in multiple languages. Wherever practical, IMDRF encourages the use of standardized, internationally recognized symbols as long as safe use of the device is not compromised by diminished understanding on the part of the user. This document provides support for the use of symbols consistent with the IMDRF objectives.

IMDRF also encourages manufacturers to employ the most appropriate methods of delivering information. Until recently, most information had been supplied as printed materials accompanying the IVD medical device. Modern technologies enable instructions for use and technical information to be provided using a more efficient means of delivery. Information can be digitally encoded on magnetic or optical media, displayed on a screen, incorporated in the device, or even transmitted over the internet at the time of use. These advances offer users the possibility of more timely availability of critical information, such as performance changes, and offer manufacturers more effective means of disseminating the information.

The ISO 18113 series specifies requirements for information supplied by the manufacturer of IVD medical devices. It consists of five parts, allowing it to address the specific needs of professional users and self-testing users in the most appropriate manner. Furthermore, since manufacturers provide different types of information for IVD reagents and instruments, their requirements are addressed in separate parts of the ISO 18113 series.

This document is not intended to be used alone. It contains terms, definitions and general principles that apply to all parts of the ISO 18113 series. While the terms and definitions in International Standards are preferred, the terms and definitions used in the information supplied by an IVD manufacturer should follow 4.6.2. Where synonyms are given, either term may be used but the first term is preferred. Some definitions had to be modified for relevance to IVD labelling or to conform to ISO terminology rules. In these cases, the source is given and indicates that the definition has been modified. In some cases, additional notes or modifications to existing notes were needed to clarify the application to IVD medical devices, and notes that did not apply to IVD medical devices were omitted.

In addition, guidelines that describe the performance characteristics of IVD medical devices are given in Annex A. This information is not repeated in the subsequent parts, therefore this document is indispensable to the application of ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5.

ISO 18113-2 specifies the requirements for labels and instructions for use supplied with IVD reagents, calibrators and control materials for professional use. ISO 18113-3 specifies the requirements for labels and instructions for use supplied with IVD instruments for professional use. ISO 18113-4 specifies the requirements for labels and instructions for use supplied with IVD reagents, calibrators and control materials for self-testing. ISO 18113-5 specifies the requirements for labels and instructions for use supplied with IVD instruments for self-testing.

ISO 18113-1 (this document), ISO 18113-2 and ISO 18113-3 are the International Standards necessary for IVD medical devices intended for medical laboratories and other professional uses; ISO 18113-1, ISO 18113-4 and ISO 18113-5 are the International Standards necessary for IVD medical devices intended for self-testing. However, recognizing that manufacturers often provide systems comprising an instrument with dedicated reagents, these International Standards allow the flexibility to provide the necessary information in the most appropriate format for the intended users, for example, a single operator's manual for an integrated IVD medical device system.

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

Part 1: Terms, definitions, and general requirements

1 Scope

This document defines concepts, establishes general principles, and specifies essential requirements for information supplied by the manufacturer of IVD medical devices.

This document does not address language requirements since that is the domain of national laws and regulations.

This document does not apply to:

a) IVD medical devices for performance evaluation (e.g. for investigational use only);

b) shipping documents;

c) material safety data sheets / Safety Data Sheets;

d) marketing information (consistent with applicable legal requirements).

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 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

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*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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/