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Diagnostični preskusni sistemi in vitro - Informacije proizvajalca (označevanje) - 1. del: Izrazi, definicije in splošne zahteve (ISO 18113-1:2009)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 1: Begriffe und allgemeine Anforderungen (ISO 18113-1:2009)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 1: Termes, définitions et exigences générales (ISO 18113-1:2009)

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In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 1: Termes, définitions et exigences générales (ISO 18113-1:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 1: Begriffe und allgemeine Anforderungen (ISO 18113-1:2009)

This European Standard was approved by CEN on 20 September 2011.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Foreword

This document (EN ISO 18113-1:2011) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2012, and conflicting national standards shall be withdrawn at the latest by October 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18113-1:2009.

This new edition contains a revised Annex ZA.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 18113-1:2009 has been approved by CEN as EN ISO 18113-1:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of the EU Directive 98/79/EC on "in vitro Diagnostic Medical Devices"

This European Standard has been prepared under a mandate given to CEN by the European Commission to provide a means of conforming to the Essential Requirements of the New Approach Directive 98/79/EC on "*in vitro* Diagnostic Medical Devices".

Once this European Standard is cited in the Official Journal of the European Union under that Directive and has been implemented as national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this European Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and European Directive 98/79/EC

Clauses of this European standard	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying comments/Notes
4.1, 4.2.1, 4.6	B.8.1.	Presumption of conformity with ER B.8.1 also requires compliance with the relevant clauses of EN ISO 18113-2, -3, -4 and -5, as applicable. Compliance with MEDDEV 2.14/3 "IVD Guidance: Supply of Instructions For Use (IFU) and other information for In vitro Diagnostic (IVD) Medical Devices – A Guide for Manufacturers and Notified Bodies" is required to ensure presumption of conformity in the case where IFU are provided separately from the IVD device. **NOTE 1**
4.3	B.8.2.	Presumption of conformity with ER B.8.2 also requires compliance with the relevant clauses of EN 980, where applicable.
4.5	B.8.4(c)	
4.8	B.8.4(j)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this European Standard.

NOTE 1 MEDDEV 2.14/3 rev 1 (2007) is available from the European Commission's website at the following address: http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_14_3_rev1_ifu_final_en.pdf .

INTERNATIONAL STANDARD

ISO 18113-1

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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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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 18113-1 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) 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 Global Harmonization Task Force (GHTF) 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 could allow patients earlier access to new technologies and treatments by decreasing the time necessary to gain regulatory compliance. See Reference [36]. This part of ISO 18113 provides a basis for harmonization of labelling requirements for IVD medical devices.

The GHTF has established guiding principles that apply to the labelling of medical devices. See Reference [36]. These principles have been incorporated into the ISO 18113 series. Of particular note, GHTF 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 part of ISO 18113 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 recognised that current national and regional usage by medical laboratories, healthcare providers, patients and regulatory authorities must be respected.

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, GHTF encourages the use of standardized, internationally recognised symbols as long as safe use of the device is not compromised by diminished understanding on the part of the user. This part of ISO 18113 provides support for the use of symbols consistent with the GHTF objectives.

GHTF 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 part of ISO 18113 is not intended to be used alone. It contains terms, definitions and general principles that apply to all parts of ISO 18113. In addition, guidelines for the terms and definitions that describe the performance characteristics of IVD medical devices are given in Annex A. This information is not repeated in the subsequent parts, so 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.

Parts 1, 2 and 3 of ISO 18113 are the International Standards necessary for IVD medical devices intended for medical laboratories and other professional uses; Parts 1, 4 and 5 of ISO 18113 are the International Standards necessary for IVD medical devices intended for self-testing. However, recognising 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 part of ISO 18113 defines concepts, establishes general principles and specifies essential requirements for information supplied by the manufacturer of IVD medical devices.

This part of ISO 18113 does not address language requirements, since that is the domain of national laws and regulations.

This part of ISO 18113 does not apply to

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

b) instrument marking,

c) material safety data sheets.

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 1000, *SI units and recommendations for the use of their multiples and of certain other units*

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 medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

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

3 Terms and definitions

For the purposes of this document and ISO 18113, Parts 2-5, the following terms and definitions apply. However, definitions provided in national and regional regulations shall take precedence. Furthermore, while the terms and definitions in International Standards are preferred, the terms and definitions used in the information supplied by an IVD manufacturer shall be subject to the requirements of 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, a note indicates that the definition has been adapted and gives the source.

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. Such cases are not considered modifications of the definition and are not identified as “adapted”.

Common English dictionary definitions apply to non-defined concepts, such as apparatus, device, constituent, equipment, evaluation, instrument, magnitude, material, part, phenomenon, property, reaction, signal, substance and system.

See Annex A for additional terms and definitions that may be used by IVD manufacturers to describe performance claims.

3.1
accessory
article intended explicitly by its manufacturer to be used together with an IVD medical device

— to enable the IVD medical device to achieve its intended purpose or

— to augment or extend the capabilities of the IVD medical device in the fulfilment of its intended purpose

NOTE Adapted from Reference [37], 5.0, Note 3.

3.2
advisory notice
communication issued by an organization, subsequent to delivery of a medical device, to provide supplementary information and/or to advise what action should be taken in

— the use of a medical device,

— the modification of a medical device,

— the return of a medical device to its manufacturer,

— the destruction of a medical device

NOTE Issue of an advisory notice might be required to comply with national or regional regulations.

[ISO 13485:2003, definition 3.3]

3.3
analyte
constituent of a sample with a measurable property

EXAMPLES In “mass of protein in 24-hour urine”, “protein” is the analyte and “mass” is the property. In “concentration of glucose in plasma”, “glucose” is the analyte and “concentration” is the property. In both cases, the full phrase designates the **measurand** (3.39).

NOTE Adapted from ISO 17511:2003, definition 3.2.

3.4
authorized representative
any natural or legal person established within a country or jurisdiction who has received a mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country's or jurisdiction's legislation

NOTE 1 In the European Union, Directive 98/79/EC [38] requires the manufacturer to designate an "EC authorized representative", established in the European Community if the manufacturer is not located in the European Community.

NOTE 2 Adapted from Reference [39].

3.5
batch
lot
defined amount of material that is uniform in its properties and has been produced in one process or series of processes

NOTE 1 The material can be either starting material, intermediate material or finished product.

NOTE 2 Adapted from EN 375:2001, definition 3.2.

3.6
batch code
lot number
distinctive set of numbers and/or letters that specifically identifies a batch and permits its manufacturing, packaging, labelling and distribution history to be traced

NOTE Adapted from EN 375:2001, definition 3.3, Reference [40], 820.3 (c), and Reference [41], Section I.

3.7
biological reference interval
reference interval

specified interval of the distribution of values taken from a biological reference population

EXAMPLE The 0,95 biological reference interval for sodium ion concentration values in serum from a population of healthy male and female adults is 135 mmol/l to 145 mmol/l.

NOTE 1 A reference interval is commonly defined as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases.

NOTE 2 A reference interval can depend upon the type of primary samples and the examination procedure used.

NOTE 3 In some cases, only one biological reference limit is important, usually an upper limit, "x", so that the corresponding biological reference interval would be less than or equal to "x".

NOTE 4 Terms such as "normal range", "normal values", and "clinical range" are ambiguous and therefore discouraged.

NOTE 5 Adapted from References [42], [43], [44] and [45].

3.8
biological reference population
reference population
group of individuals in a well-defined state of health or disease

NOTE 1 When biological reference intervals are provided by a manufacturer in the instructions for use, laboratories using the IVD medical device are responsible for verifying that the biological reference populations represent the populations serviced by the laboratories.

NOTE 2 A biological reference population can be a defined homogenous group of apparently healthy individuals or individuals with a specific medical condition. The concept allows for relating the reference interval to age, gender and ethnicity of the reference population, as appropriate.

NOTE 3 Adapted from References [42], [43], [44] and [45].