In vitro meditsiinilised diagnostikaseadmed. Tootja poolt antav teave (etikettimine). Osa 1: Terminid, määratlused ja üldnõuded

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 18113-1:2010 sisaldab Euroopa standardi EN ISO 18113-1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 18113-1:2010 consists of the English text of the European standard EN ISO 18113-1:2009.
Standard on kinnitatud Eesti Standardikeskuse 28.02.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 28.02.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.12.2009.	Date of Availability of the European standard text 15.12.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.100.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18113-1

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English Version

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 18 November 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 18113-1:2009: E

Foreword

This document (EN ISO 18113-1:2009) 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 June 2010, and conflicting national standards shall be withdrawn at the latest by December 2012.

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 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, 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 the United Kingdom.

Endorsement notice

The text of ISO 18113-1:2009 has been approved by CEN as a EN ISO 18113-1:2009 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 International 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 confers, within the limits of the scope of this International Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

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

Clause(s)/subclause(s) of this International Standard	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
This Standard	B.7, B.8.1, B.8.2, B.8.3, B.8.4, B.8.7	
4.1	B.8.1	
4.3	B.8.2	
4.5	B.8.4 (c)	
4.6	B.8.1, B.8.7	NOTE 1 Compliance with MEDDEV 2.14/3, IVD Guidances: 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 cases where IFU are provided separately from the device. NOTE 2 Essential requirement B.8.7 of Directive 98/79/EC should be consulted for a comprehensive list of the information required.
4.6.4	B.8.7 (u)	
4.8	B.8.3, B.8.4 (j), B.8.7 (s)	NOTE Essential requirement B.8.3 of Directive 98/79/EC should be consulted for a comprehensive list of the information required
4.9	B.8.4 (b)	

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

NOTE 1 In the European Union, Directive 98/79/EC requires the manufacturer to designate an “EC authorized representative”, established in the European Community if the manufacturer is not located in the European Community. In those instances, notes within this standard which refer to Authorized representatives should be considered in Europe as normative, not informative.

NOTE 2 MEDDEV 2.14/3 rev 1 (2007) is available from the European Commission's website at the following address: http://ec.europa.eu/enterprise/medical_devices/meddev/2_14_3_rev1_ifu_final.pdf.

Contents

Page

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*