

In vitro meditsiinilised diagnostikaseadmed. Tootja poolt antav teave (etikettimine). Osa 5: Enesekontrolliks mõeldud in vitro diagnostilised instrumendid (ISO 18113-5:2009)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 18113-5:2011 sisaldab Euroopa standardi EN ISO 18113-5:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 18113-5:2011 consists of the English text of the European standard EN ISO 18113-5:2011.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.10.2011.	Date of Availability of the European standard is 19.10.2011.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.100.10

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Aru 10, 10317 Tallinn, Eesti; www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:
Aru 10, 10317 Tallinn, Estonia; www.evs.ee; phone 605 5050; e-mail info@evs.ee

English Version

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 5: Instruments de diagnostic in vitro pour auto-tests (ISO 18113-5:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 5: Geräte für in-vitro-diagnostische Untersuchungen zur Eigenanwendung (ISO 18113-5:2009)

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

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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.



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 18113-5:2011) 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 18113-5:2009.

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 18113-5:2009 has been approved by CEN as EN ISO 18113-5:2011 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
6, 7.3, 7.11	B.7	These clauses only cover the second sentence of ER B.7, namely the labelling requirements. NOTE 2
7.12	B.7.2	
5, 6, 7	B.8.1	Presumption of conformity with ER B.8.1 also requires compliance with clauses 4.1, 4.2.1 and 4.6 of EN ISO 18113-1.
5.2.1	B.8.4(b)	
5.2.2	B.8.4(d)	Full compliance to ER B.8.4(d) requires the use of EN 980, clause 5.4 symbol (LOT) or EN 980, clause 5.5 symbol (SN), as applicable.
5.2.3	B.8.4(g)	
7.3	B.8.5	
6, 7.1, 7.2, 7.3, 7.4, 7.5, 7.11	B.8.7(a)	Presumption of conformity with ER B.8.7(a) requires also compliance with clause 4.5 of EN ISO 18113-1. NOTE 1, NOTE 2
7.8	B.8.7(d)	
7.2.2, 7.10	B.8.7(e)	
7.10	B.8.7(f)	
7.11, 7.14, 7.15	B.8.7(g)	NOTE 2
7.7, 7.8, 7.9, 7.10, 7.11	B.8.7(h)	NOTE 2
7.18	B.8.7(j)	
7.12, 7.14	B.8.7(k)	

Clauses of this European Standard	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying comments/Notes
7.6, 7.10	B.8.7(m)	
7.6, 7.10, 7.14, 7.16, 7.17	B.8.7(n)	
7.10	B.8.7(o)	
7.5, 7.16	B.8.7(s)	NOTE 2
7.7, 7.12, 7.13, 7.14, 7.18, 7.19	B.8.7(t)	

NOTE 1 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 European Union.

NOTE 2 Essential Requirement B.8.7 of Directive 98/79/EC should be consulted for a comprehensive list of the information required.

Contents

Page

Foreword	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions	2
4 Essential requirements	2
5 Labels and marking.....	2
5.1 General	2
5.2 Identification of the IVD instrument.....	2
6 Elements of the instructions for use	3
7 Content of the instructions for use	3
7.1 Manufacturer.....	3
7.2 Identification of the IVD instrument.....	3
7.3 Intended use	4
7.4 Storage and handling.....	4
7.5 Warnings and precautions	4
7.6 Instrument installation	4
7.7 Principles of measurement	5
7.8 Performance of the IVD instrument.....	5
7.9 Limitations of use.....	5
7.10 Preparation prior to operation	5
7.11 Operating procedure	5
7.12 Control procedure	6
7.13 Reading of examination results	6
7.14 Special functions.....	6
7.15 Shut-down procedure	6
7.16 Disposal information.....	6
7.17 Maintenance.....	7
7.18 Troubleshooting	7
7.19 Follow-up action	7
Bibliography.....	8

Introduction

Manufacturers of *in vitro* diagnostic (IVD) instruments for self-testing supply users with information to enable the safe use and expected performance of their devices. Adequate instructions for use are essential for the safe and proper operation of IVD instruments. 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 [7]. This part of ISO 18113 provides a basis for harmonization of labelling requirements for IVD instruments for self-testing.

This part of ISO 18113 is concerned solely with information supplied with IVD instruments and equipment 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 592^[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 instruments that are intended to be used as a system with reagents provided by the same manufacturer, this part of ISO 18113 is also intended to be used together with ISO 18113-1 and ISO 18113-4^[3].

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

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

1 Scope

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

This part of ISO 18113 also applies to apparatus and equipment intended to be used with IVD instruments for self-testing.

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

This part of ISO 18113 does not apply to

- a) instructions for instrument servicing or repair,
- b) IVD reagents, including calibrators and control materials for use in control of the reagent,
- c) IVD instruments 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*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements*

IEC 61010-2-101, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment*

IEC 61326-2-6, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment*

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

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