

**In vitro diagnostika meditsiiniseadmed. Tootja poolt antav teave (etikettimine). Osa 2: In vitro diagnostika reagentid professionaalseks kasutuseks**

**In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)**

## EESTI STANDARDI EESSÕNA

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English Version

**In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)**

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 2: Réactifs de diagnostic in vitro à usage professionnel (ISO 18113-2:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 2: In-vitro-diagnostische Reagenzien für den Gebrauch durch Fachpersonal (ISO 18113-2:2009)

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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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Foreword

This document (EN ISO 18113-2:2011) 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of an identical text or by endorsement, at the latest by April 2012, and conflicting national standards shall be withdrawn at the latest by October 2014.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 18113-2:2009.

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 18113-2:2009 has been approved by CEN as EN ISO 18113-2:2011 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 Directive 98/79/EC**

Clauses of this European Standard	Essential requirements (ERs) of Directive 98/79/EC	Qualifying comments/Notes
7.7	B.3.1	This standard only covers the second sentence of ER B.3.1 namely the labelling requirements.
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.
5.8, 6.8, 7.10	B.8.3	<b>NOTE 2</b>
5.1, 6.2	B.8.4 (a)	<b>NOTE 1</b>
5.2.1, 5.3, 6.3.1, 6.4	B.8.4 (b)	
5.2.2, 6.3.2	B.8.4 (d)	Full compliance with ER B.8.4 (d) requires the use of EN 930, clause 5.4: symbol (LOT).
5.7, 6.7	B.8.4 (e)	
5.5, 6.5	B.8.4 (g)	
5.6, 6.6	B.8.4 (h)	
5.8, 6.8	B.8.4 (j)	<b>NOTE 2</b>
5.4, 7.3	B.8.5	
5.2.2, 6.3.2	B.8.6	
7.1, 7.2, 7.9, 7.10	B.8.7 (a)	Presumption of conformity with ER B.8.7 (a) requires also compliance with EN ISO 18113-1, clause 4.5, as well as an indication of the in vitro use of the device. <b>NOTE 1, NOTE 3</b>
7.6	B.8.7 (b)	
7.9	B.8.7 (c)	<b>NOTE 3</b>
7.16	B.8.7 (d)	
7.7	B.8.7 (e)	
7.11	B.8.7 (f)	

Clauses of this European Standard	Essential requirements (ERs) of Directive 98/79/EC	Qualifying comments/Notes
7.12	B.8.7 (g)	
7.4, 7.8, 7.16, 7.18	B.8.7 (h)	Full compliance with ER B.8.7 (h) requires, where applicable, an indication of any particular training needed to operate the device.
7.14, 7.15	B.8.7 (i)	
7.18, 7.13	B.8.7 (j)	
7.5, 7.13	B.8.7 (k)	
7.17	B.8.7 (l)	
7.7	B.8.7 (m)	
7.8	B.8.7 (o)	
7.10	B.8.7 (r)	<b>NOTE 3</b>
7.10	B.8.7 (s)	<b>NOTE 3</b>

**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.8.3 of Directive 98/79/EC should be consulted for a comprehensive list of the information required.

**NOTE 3** Essential requirement B.8.7 of Directive 98/79/ EC should be consulted for a comprehensive list of the information required.

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## Introduction

Manufacturers of *in vitro* diagnostic (IVD) reagents for professional use supply users with information to enable their safe use and the expected performance of their devices. 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 [9]. This part of ISO 18113 provides a basis for harmonization of labelling requirements for IVD reagents for professional use.

This part of ISO 18113 is concerned solely with information supplied with IVD reagents, calibrators and control materials intended for professional use. 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 375:2001<sup>[5]</sup>. The text has been modified to conform to Part 2 of the ISO/IEC Directives<sup>[4]</sup>, 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 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 part of ISO 18113 is also intended to be used together with ISO 18113-1 and ISO 18113-3<sup>[2]</sup>.



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

## **Part 2: *In vitro* diagnostic reagents for professional use**

### **1 Scope**

This part of ISO 18113 specifies requirements for information supplied by the manufacturer of IVD reagents for professional use.

This part of ISO 18113 also applies to information supplied by the manufacturer with calibrators and control materials intended for use with IVD medical devices for professional use.

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

This part of ISO 18113 applies to the labels for outer and immediate containers and to the instructions for use.

This part of ISO 18113 does not apply to

- a) IVD instruments or equipment,
- b) IVD reagents for self-testing.

### **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 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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*

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

### **3 Terms and definitions**

For the purposes of this document, the terms and definitions given in ISO 18113-1 apply.