NSAI Standards

Irish Standard
I.S. EN ISO 18113-4:2009

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113 -4:2009)

I.S. EN ISO 18113-4:2009

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Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 18113-4

December 2009

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Supersedes EN 376:2002

English Version

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 4: Réactifs de diagnostic in vitro pour auto-tests (ISO 18113-4:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 4: Reagenzien für in-vitro-diagnostische Untersuchungen zur Eigenanwendung (ISO 18113-4:2009)

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
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 18113-4:2009: E

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Foreword

This document (EN ISO 18113-4:2009) 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 supersedes EN 376:2002.

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 18113-4:2009 has been approved by CEN as a EN ISO 18113-4:2009 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 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 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
4.1	B.8.1, B.8.2	
4.2	B.8.1, B.8.2	
4.3	B.7, B.8.1, B.8.2	
5.1	B.8.4 (a)	See Note 1.
5.2.1	B.8.4 (b)	
5.2.2	B.8.4 (d), B.8.6	
5.3	B.8.4 (b)	
5.4	B.8.5	
5.5	B.8.4 (g)	
5.6	B.8.4 (h)	
5.7	B.8.4 (e)	
5.8	B.8.3, B.8.4 (j)	See Note 2.
6.1	B.7, B.8.1, B.8.2	
6.2	B.8.4 (a)	
6.3.1	B.8.4 (b)	

Table ZA (continued)

Clause(s)/subclause(s) of this International Standard	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
6.3.2	B.8.4 (d), B.8.6	
6.4	B.8.4 (b)	
6.5	B.8.4 (g)	
6.6	B.8.4 (h)	
6.7	B.8.4 (e)	
6.8	B.8.3, B.8.4 (j)	See Note 2.
7.1	B.8.7 (a)	See Notes 1 and 3.
7.2	B.8.7 (a)	
7.3	B.7, B.8.5	
7.4	B.8.7 (h)	
7.5	B.8.7 (b)	
7.6	B.3.1, B.8.7 (e), B.8.7 (m)	
7.7	B.8.7 (h)	
7.8	B.8.7 (a), B.8.7 (c)	
7.9	B.8.7 (a), B.8.7 (s)	
7.10	B.8.7 (f)	
7.11	B.7, B.8.7 (g)	
7.12	B.8.7 (k)	See Note 3.
7.13	B.8.7 (t)	
7.14	B.8.7 (t)	
7.15	B.8.7 (t)	
7.16	B.8.7 (t)	
7.17	B.8.7 (t)	

GENERAL NOTE The presumption of conformity depends on applying all relevant requirements of ISO 18113-1.

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.

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

I.S. EN ISO 18113-4:2009

INTERNATIONAL STANDARD

ISO 18113-4

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

Part 4: *In vitro* diagnostic reagents for self-testing

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

Partie 4: Réactifs de diagnostic in vitro pour auto-tests

Reference number
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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 18113-4 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) reagents for self-testing supply users with information to enable the safe use and 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 self-testing.

This part of ISO 18113 is concerned solely with information supplied with IVD reagents, calibrators and control materials 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 376:2002[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 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 18113-5[3].

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

Part 4: *In vitro* diagnostic reagents for self-testing

1 Scope

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

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 self-testing.

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 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*

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.