



NSAI
Standards

Irish Standard
I.S. EN ISO 18113-5:2011

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

I.S. EN ISO 18113-5:2011

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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)

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**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”4**

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of an identical text or by endorsement, at the latest by April 2012, and conflicting national standards shall be withdrawn at the latest by December 2012.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 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.

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**INTERNATIONAL
STANDARD**

**ISO
18113-5**

First edition
2009-12-15

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

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

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

Partie 5: Instruments de diagnostic in vitro pour auto-tests



Reference number
ISO 18113-5:2009(E)

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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 18113-5 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) 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].

I.S. EN ISO 18113-5:2011

***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*

3 Terms and definitions

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

4 Essential requirements

The requirements of ISO 18113-1 apply.

ISO standards for specific IVD medical devices may also contain requirements for information supplied by the manufacturer.

EXAMPLES ISO 15197^[1]; ISO 17593, ^[2].

5 Labels and marking

5.1 General

The requirements of IEC 61010-1, IEC 61010-2-101 and IEC 61326-2-6 concerning labels and markings apply.

For the use of symbols, the requirements of ISO 15223-1 and EN 980 apply.

5.2 Identification of the IVD instrument

5.2.1 IVD instrument name

The name of the IVD instrument shall be given.

When the name does not uniquely identify the IVD instrument, an additional means of identification shall also be given.

EXAMPLES Catalogue number, commodity number.

5.2.2 Serial number

A unique serial number shall be given for IVD instruments.

NOTE All instruments covered by IEC 61010 require serial numbers.

Where serial numbers are not practical for apparatus, equipment or accessories intended to be used with IVD instruments, a batch code may be used instead.

EXAMPLE A primary sample receptacle would be assigned a batch code.

5.2.3 *In vitro* diagnostic use

The *in vitro* diagnostic use of the instrument shall be indicated when required by regulation.

EXAMPLES "For *in vitro* diagnostic use" or graphical symbol: "*in vitro* diagnostic medical device".

6 Elements of the instructions for use

IVD instruments for self-testing shall be supplied with easy to understand instructions for use.

The instructions for use for IVD instruments for self-testing shall include the following, where appropriate:

- a) table of contents;
- b) overview of operating elements;
- c) flow and block diagrams of instrument configuration;
- d) integration and arrangement of text and illustrations;
- e) graphic emphasis of warnings;
- f) examples of how to use the instrument;
- g) diagrams of procedural steps;
- h) list of accessories;
- i) an index;
- j) version control identification and first date of applicability.

NOTE Recommendations for developing user instruction manuals for medical devices used in home health care are found in Reference [8].

If a manufacturer provides a complete system containing reagents and instrument, required information may alternatively be included in the instructions for use for the reagents or in a combined manual for the system.

7 Content of the instructions for use

7.1 Manufacturer

The name and address of the manufacturer shall be given.

NOTE In the European Union, the name and address of the manufacturer's "EC Authorized Representative" is also required if the legal manufacturer is not located within the EU. (See Reference [6].)

7.2 Identification of the IVD instrument

7.2.1 IVD instrument name

The name of the IVD instrument shall be given.

When the name does not uniquely identify the IVD instrument, an additional means of identification shall also be given.

EXAMPLES Catalogue number, commodity number.

7.2.2 Module and software identification

Separate instrument modules and/or software shall be identified by name and, if applicable, version.

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