ILNAS

Institut luxembourgeois de la normalisation
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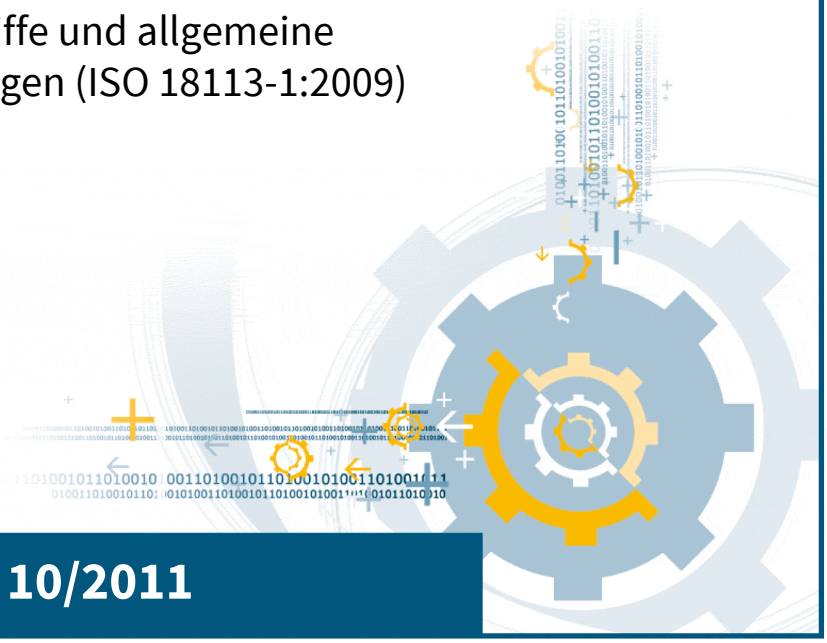
des produits et services

ILNAS-EN ISO 18113-1:2011

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 1: Termes, définitions et exigences générales (ISO

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 1: Begriffe und allgemeine Anforderungen (ISO 18113-1:2009)



10/2011

National Foreword

This European Standard EN ISO 18113-1:2011 was adopted as Luxembourgish Standard ILNAS-EN ISO 18113-1:2011.

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 18113-1

October 2011

ICS 11.100.10

Supersedes EN ISO 18113-1:2009

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 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

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Foreword

This document (EN ISO 18113-1:2011) 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 18113-1:2009.

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 18113-1:2009 has been approved by CEN as EN ISO 18113-1:2011 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
4.1, 4.2.1, 4.6	B.8.1.	Presumption of conformity with ER B.8.1 also requires compliance with the relevant clauses of EN ISO 18113-2, -3, -4 and -5, as applicable. Compliance with MEDDEV 2.14/3 "IVD Guidance: 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 case where IFU are provided separately from the IVD device. **NOTE 1**
4.3	B.8.2.	Presumption of conformity with ER B.8.2 also requires compliance with the relevant clauses of EN 980, where applicable.
4.5	B.8.4(c)	
4.8	B.8.4(j)	

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

NOTE 1 MEDDEV 2.14/3 rev 1 (2007) is available from the European Commission's website at the following address: http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_14_3_rev1_ifu_final_en.pdf .

INTERNATIONAL STANDARD

ISO 18113-1

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

Part 1: Terms, definitions and general requirements

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Partie 1: Termes, définitions et exigences générales

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