DIN EN ISO 18113-2

DIN

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Supersedes
DIN EN ISO 18113-2:2010-05
See start of application

In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009); English version EN ISO 18113-2:2011, English translation of DIN EN ISO 18113-2:2013-01

In-vitro-Diagnostika –
Bereitstellung von Informationen durch den Hersteller –
Teil 2: *In-vitro*-diagnostische Reagenzien für den Gebrauch durch Fachpersonal (ISO 18113-2:2009);
Englische Fassung EN ISO 18113-2:2011,
Englische Übersetzung von DIN EN ISO 18113-2:2013-01

Dispositifs médicaux de diagnostic *in vitro* –
Informations fournies par le fabricant (étiquetage) –
Partie 2: Réactifs de diagnostic *in vitro* à usage professionel (ISO 18113-2:2009);
Version anglaise EN ISO 18113-2:2011,
Traduction anglaise de DIN EN ISO 18113-2:2013-01

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In case of doubt, the German-language original shall be considered authoritative.

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A comma is used as the decimal marker.

Start of application

The start of application of this standard is 2013-01-01.

DIN EN ISO 18113-2:2010-05 may be used in parallel until 2014-10-31.

National foreword

This standard (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" (Secretariat: DIN, Germany). The responsible German body involved in its preparation was the *Normenausschuss Medizin* (Medical Standards Committee), Working Committee NA 063-03-03 AA *Qualitätsmanagement in medizinischen Laboratorien*.

DIN EN 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

The DIN Standards corresponding to the International Standards referred to in this document are as follows:

ISO 8601	DIN ISO 8601
ISO 14971	DIN EN ISO 14971
ISO 15223-1	DIN ISO 15223-1
ISO 18113-1	DIN EN ISO 18113-1
ISO 18113-3	DIN EN ISO 18113-3

Amendments

This standard differs from DIN EN ISO 18113-2:2010-05 as follows:

a) Annex ZA has been revised and rendered more precise.

Previous editions

DIN EN 375: 1992-07, 2001-06
DIN EN ISO 18113-2: 2010-05

National Annex NA
(informative)

Bibliography

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

DIN EN ISO 14971, *Medical devices — Application of risk management to medical devices*

DIN ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

DIN EN ISO 18113-1, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements*

DIN EN ISO 18113-3, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use*