DIN EN ISO 18113-3

DIN

ICS 11.100.10

Supersedes
DIN EN ISO 18113-3:2010-05
See start of application

In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 3: *In vitro* diagnostic instruments for professional use (ISO 18113-3:2009); English version EN ISO 18113-3:2011, English translation of DIN EN ISO 18113-3:2013-01

In-vitro-Diagnostika –
Bereitstellung von Informationen durch den Hersteller –
Teil 3: Geräte für *in-vitro*-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal (ISO 18113-3:2009);
Englische Fassung EN ISO 18113-3:2011,
Englische Übersetzung von DIN EN ISO 18113-3:2013-01

Dispositifs médicaux de diagnostic *in vitro* –
Informations fournies par le fabricant (étiquetage) –
Partie 3: Instruments de diagnostic *in vitro* à usage professionel (ISO 18113-3:2009);
Version anglaise EN ISO 18113-3:2011,
Traduction anglaise de DIN EN ISO 18113-3:2013-01

Document comprises 19 pages

Translation by DIN-Sprachendienst.
In case of doubt, the German-language original shall be considered authoritative.

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 18113-3:2010-05 may be used in parallel until 2014-10-31.

National foreword

This standard (EN ISO 18113-3:2011) 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 14971	DIN ISO 14971
ISO 15223-1	DIN ISO 15223-1
ISO 18113-1	DIN EN ISO 18113-1
ISO 18113-2	DIN EN ISO 18113-2
IEC 61010-1	DIN EN 61010-1
IEC 61326-2-6	DIN EN 61326-2-6
IEC 62366	DIN EN 62366

Amendments

This standard differs from DIN EN ISO 18113-3:2010-05 as follows:

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

Previous editions

DIN EN 591: 1994-11, 2001-07
DIN EN ISO 18113-3: 2010-05

National Annex NA
(informative)

Bibliography

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 18113-2, *In vitro diagnostic medical devicess — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use*

DIN EN 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*

DIN EN 61326-2-6, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment*

DIN EN 62366, *Medical devices — Application of usability engineering to medical devices*

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