ICS 11.100.10 SLOVENSKÁ TECHNICKÁ NORMA September 2024

STN	**Diagnostické zdravotnícke pomôcky in vitro Informácie dodávané výrobcom (označovanie) Časť 2: Diagnostické činidlá in vitro na profesionálne používanie (ISO 18113-2: 2022)**	**STN EN ISO 18113-2** 85 1001

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/24

Obsahuje: EN ISO 18113-2:2024, ISO 18113-2:2022

Oznámením tejto normy sa od 30.06.2027 ruší
STN EN ISO 18113-2 (85 1001) z februára 2012

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 18113-2

June 2024

ICS 11.100.10 Supersedes EN ISO 18113-2:2011

English Version

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 2: Réactifs de diagnostic in vitro à usage professionnel (ISO 18113-2:2022)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 2: In-vitro-diagnostische Reagenzien für den Gebrauch durch Fachpersonal (ISO 18113-2:2022)

This European Standard was approved by CEN on 2 October 2022.

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 18113-2:2024) has been prepared by Technical Committee ISO/TC 212 "Medical laboratories and in vitro diagnostic 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 December 2024, and conflicting national standards shall be withdrawn at the latest by June 2027.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18113-2:2011.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 18113-2:2022 has been approved by CEN as EN ISO 18113-2:2024 without any modification.

Annex ZA
(informative)

Relationship between this European Standard the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning in vitro diagnostic medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/746, the definitions set out in this Regulation prevail.

This document needs to be considered together with the other parts of EN ISO 18113-series to fully apply the concepts of this labelling standard series. EN ISO 18113-1 provides definitions and overall concepts which may be further applied or directed to specific device format and labelling location.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the In vitro Diagnostic Regulation (EU) 2017/746).

Where the standard includes notes that require alignment to local or regional regulations, all clauses need to be read in the context of Regulation (EU) 2017/746.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/746. This means that risks have to be ‘reduced as far as possible’, ‘reduced to a level as low as reasonably practicable’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ‘prevented’ or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Regulation (EU) 2017/746 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
20.2 a)	5.2.1, 6.3.1	Covered
20.2 (b)	5.2.1., 5.4., 6.3.1,	Covered
20.2 c)	5.1, 6.2	Covered
20.2 e)	5.5, 6.5	Covered with respect to the indication of in-vitro diagnostic medical device
20.2 f)	5.2.2, 6.3.2	Covered
20.2 h)	5.7, 6.7	Covered
20.2 j)	5.3	Covered
20.2 k)	5.6, 6.6	Covered
20.2 q)	5.4	Covered with respect to indication that the device is intended for near patient testing
20.2 t)	5.2.2, 6.3.2	Covered with respect to identification of the components by batch code
20.4.1 a)	7.2.	Covered
20.4.1 b)	7.2	Covered
20.4.1 c) i)	7.3 1st bullet	Covered
20.4.1 c) ii)	7.3 4th bullet	Covered
20.4.1 c) iii)	7.3 6th bullet	Covered with respect to the impairment, condition, or predisposition
20.4.1 c) iv)	7.3 8th bullet	Covered
20.4.1 c) v)	7.3 5th bullet	Covered with respect to qualitative and quantitative examinations
20.4.1 c) vi)	7.3 3rd bullet	Covered
20.4.1 c) vii)	7.3 2nd bullet	Covered
20.4.1 e)	7.3 7th bullet	Covered
20.4.1 f)	7.4	Covered

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
20.4.1 h)	7.6, 7.10	Covered with respect to the nature, amount, concentration of the reactive ingredients, Covered with respect to limitations of use
20.4.1 i)	7.6, 7.7	Covered
20.4.1 j)	7.7	Covered with respect to listing further equipment and ensuring proper and safe combination for use
20.4.1 k)	7.9., 7.10	Covered with respect to storage
20.4.1 l)	7.9	Covered
20.4.1 n) i)	7.10., 1st bullet	Covered
20.4.1 n) ii)	7.10,	Covered
20.4.1 n) v)	7.10 last sentence	Covered
20.4.1 o)	7.10, 6th indent	Covered
20.4.1 q)	7.11	Covered
20.4.1 r)	7.8	Covered with respect to reagent preparation.
20.4.1 t)	7.13	Covered
20.4.1 u)	7.5	Covered
20.4.1. v)	7.5, 7.14, 7.15	Covered
20.4.1 w)	7.16.1	Covered with respect to describing analytical performance characteristics relevant to the intended uses
20.4.1. x)	7.16.2	Covered with respect to diagnostic sensitivity and specificity
20.4.1 y)	7.14	Covered
20.4.1. z)	7.16.2	Covered
20.4.1 aa)	7.17	Covered
20.4.1 ab)	7.18	Covered

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
20.4.1 ac) i)	7.10.	Covered.
20.4.1 ad)	7.1	Covered
20.4.1 ae)	7.20	Covered with respect to document and change control

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 8601-1	ISO 8601-1:2019	Date and time — Representations for information interchange — Part 1: Basic rules	For applicable standard edition see Column 2
ISO 8601-2	ISO 8601-2:2019	Representations for information interchange — Part 2: Extensions	For applicable standard edition see Column 2
ISO 14971	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021
ISO 15223-1	ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	EN ISO 15223-1:2021
ISO 18113-1	ISO 18113-1:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements	EN ISO 18113-1:2024

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document and are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 18113-2

Second edition
2022-10

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

Part 2: In vitro diagnostic reagents for professional use

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

Partie 2: Réactifs de diagnostic in vitro à usage professionnel

Reference number
ISO 18113-2:2022(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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 18113-2:2009), which has been technically revised.

The main changes are as follows:

— Added Information pertaining to (unique device identifier-device identifier) UDI;

— Updated with examples to reference European Union and other regulations;

— Added additional detail for clarification;

— Updated the Bibliography.

A list of all parts in the ISO 18113 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Manufacturers of in vitro diagnostic (IVD) reagents for professional use, supply users with information to enable the safe use and the expected performance of their devices. The type and level of detail varies according to the intended uses and country-specific regulations.

The International Medical Devices Regulators Forum (IMDRF) encourages convergence of the evolution of regulatory systems for medical devices at the global level. Eliminating differences among regulatory jurisdictions can allow patients earlier access to new technologies and treatments. This document provides a basis for harmonization of labelling requirements for IVD reagents for professional use.

This document is concerned solely with information supplied with IVD reagents, calibrators and control materials intended for professional use. 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 document is intended to support the essential labelling requirements of all the IMDRF[8] partners, as well as other countries that have 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 document is also intended to be used together with ISO 18113-1 and ISO 18113-3.

INTERNATIONAL STANDARD ISO 18113-2:2022(E)

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

Part 2: In vitro diagnostic reagents for professional use

1 Scope

This document specifies requirements for information supplied by the manufacturer of in vitro diagnostic (IVD) reagents, calibrators and controls intended for professional use.

This document can also be applicable to accessories.

This document is applicable to the labels for outer and immediate containers and to the instructions for use.

This document does not apply to:

a) IVD instruments or equipment;

b) IVD reagents for self-testing.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

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

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — 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*