SLOVENSKI STANDARD
SIST EN ISO 18113-1:2024

01-september-2024

In vitro diagnostični preskusni sistemi - Informacije proizvajalca (označevanje) - 1. del: Izrazi, definicije in splošne zahteve (ISO 18113-1:2022)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 1: Begriffe und allgemeine Anforderungen (ISO 18113-1:2022)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 1: Termes, définitions et exigences générales (ISO 18113-1:2022)

Ta slovenski standard je istoveten z: **EN ISO 18113-1:2024**

ICS:

01.040.11	Zdravstveno varstvo (Slovarji)	Health care technology (Vocabularies)
11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 18113-1:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18113-1

June 2024

ICS 11.100.10

Supersedes EN ISO 18113-1:2011

English Version

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 1: Termes, définitions et exigences générales (ISO 18113-1:2022)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 1: Begriffe und allgemeine Anforderungen (ISO 18113-1:2022)

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

Ref. No. EN ISO 18113-1:2024 E

Contents

Page

European foreword

This document (EN ISO 18113-1:2024) 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 18113-1:2011.

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 18113-1:2022 has been approved by CEN as EN ISO 18113-1:2024 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
20.1. a)	4.1.1, 4.6.2	Covered
20.1. d)	4.6.1	Covered
20.1. d)	4.6.6	Covered with respect to clarifying that IFU can supplied either in hard copy or electronic format
20.1 f)	4.6.6, 4.6.7, 4.6.8	Covered with respect to other formats of IFU except for near patient testing. Note that the clauses cited here apply only for professional-use devices as per the note within section 4.6.6. when applied to Regulation (EU) 2017/746.
20.1. g)	4.8.1, 4.8.2, 4.8.3	Covered with respect to the intended users of the device
20.1. h)	4.3.1 – 4.3.3	Covered
20.4.1. ad)	4.10 Assistance	Covered with respect to instructions on how to obtain assistance.

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 13485	ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes	EN ISO 13485:2016 EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021
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
IEC 62366-1	IEC 62366-1:2015 IEC 62366-1:2015/Cor 1:2016 IEC 62366-1:2015/A1:2020	Medical devices — Part 1: Application of usability engineering to medical devices	EN 62366-1:2015 EN 62366-1:2015/AC:2015 EN 62366-1:2015/A1:2020

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 18113-1

Second edition
2022-10

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

Part 1: Terms, definitions, and general requirements

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

Partie 1: Termes, définitions et exigences générales

Reference number
ISO 18113-1:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 18113-1:2009), which has been technically revised.

The main changes are as follows:

— Updated terms and definitions;

— References to the UDI (Unique Device Identifier/Identification) requirement added;

— Updated Bibliography to align with updates of standards and publications;

— Updated to align with European Union and other regulations;

— Added additional detail for clarification.

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) medical devices supply users with information to enable the safe use and expected performance of their devices. Traditionally, this information has been provided in the form of labels, package inserts and user manuals, where the type and level of detail would depend on the intended uses and country-specific regulations.

The International Medical Device Regulators Forum (IMDRF) encourages convergence of the evolution of regulatory systems for medical devices at the global level. The goal is to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means. Consistent worldwide labelling requirements offer significant benefits to manufacturers, users, patients and regulatory authorities. Eliminating differences among regulatory jurisdictions can allow patients earlier access to new technologies and treatments by decreasing the time necessary to gain regulatory compliance. This document provides a basis for harmonization of labelling requirements for IVD medical devices. As per ISO 20417, the ISO 18113 series represents a group standard and, therefore, has precedence with regards to the labelling requirements for IVDs.

The Global Harmonization Task Force (GHTF) now replaced by IMDRF (See Reference [52]) has established guiding principles that apply to the labelling of medical devices and IVDs. These principles have been incorporated into the ISO 18113 series. Of particular note, IMDRF states that country-specific requirements for the content, wording and format of labels and instructions for use should be kept to a minimum and eliminated over time as the opportunities arise.

This document contains a comprehensive list of terms and definitions necessary to develop the labelling for IVD medical devices. Internationally agreed-upon definitions of important concepts promote greater consistency in IVD medical device labelling. While the goal is to standardize the terminology used in IVD medical device labelling to the extent possible, it is also recognized that current national and regional usage by medical laboratories, healthcare providers, patients and regulatory authorities should be taken into consideration

An obstacle to the timely and affordable availability of IVD medical devices in some countries is the requirement for information to appear in multiple languages. Wherever practical, IMDRF encourages the use of standardized, internationally recognized symbols as long as safe use of the device is not compromised by diminished understanding on the part of the user. This document provides support for the use of symbols consistent with the IMDRF objectives.

IMDRF also encourages manufacturers to employ the most appropriate methods of delivering information. Until recently, most information had been supplied as printed materials accompanying the IVD medical device. Modern technologies enable instructions for use and technical information to be provided using a more efficient means of delivery. Information can be digitally encoded on magnetic or optical media, displayed on a screen, incorporated in the device, or even transmitted over the internet at the time of use. These advances offer users the possibility of more timely availability of critical information, such as performance changes, and offer manufacturers more effective means of disseminating the information.

The ISO 18113 series specifies requirements for information supplied by the manufacturer of IVD medical devices. It consists of five parts, allowing it to address the specific needs of professional users and self-testing users in the most appropriate manner. Furthermore, since manufacturers provide different types of information for IVD reagents and instruments, their requirements are addressed in separate parts of the ISO 18113 series.

This document is not intended to be used alone. It contains terms, definitions and general principles that apply to all parts of the ISO 18113 series. While the terms and definitions in International Standards are preferred, the terms and definitions used in the information supplied by an IVD manufacturer should follow 4.6.2. Where synonyms are given, either term may be used but the first term is preferred. Some definitions had to be modified for relevance to IVD labelling or to conform to ISO terminology rules. In these cases, the source is given and indicates that the definition has been modified. In some cases, additional notes or modifications to existing notes were needed to clarify the application to IVD medical devices, and notes that did not apply to IVD medical devices were omitted.

In addition, guidelines that describe the performance characteristics of IVD medical devices are given in Annex A. This information is not repeated in the subsequent parts, therefore this document is indispensable to the application of ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5.

ISO 18113-2 specifies the requirements for labels and instructions for use supplied with IVD reagents, calibrators and control materials for professional use. ISO 18113-3 specifies the requirements for labels and instructions for use supplied with IVD instruments for professional use. ISO 18113-4 specifies the requirements for labels and instructions for use supplied with IVD reagents, calibrators and control materials for self-testing. ISO 18113-5 specifies the requirements for labels and instructions for use supplied with IVD instruments for self-testing.

ISO 18113-1 (this document), ISO 18113-2 and ISO 18113-3 are the International Standards necessary for IVD medical devices intended for medical laboratories and other professional uses; ISO 18113-1, ISO 18113-4 and ISO 18113-5 are the International Standards necessary for IVD medical devices intended for self-testing. However, recognizing that manufacturers often provide systems comprising an instrument with dedicated reagents, these International Standards allow the flexibility to provide the necessary information in the most appropriate format for the intended users, for example, a single operator's manual for an integrated IVD medical device system.