SLOVENSKI STANDARD
oSIST prEN ISO 18113-1:2021

01-oktober-2021

In vitro diagnostični preskusni sistemi - Informacije proizvajalca (označevanje) - 1. del: Izrazi, definicije in splošne zahteve (ISO/DIS 18113-1:2021)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO/DIS 18113-1:2021)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 1: Begriffe und allgemeine Anforderungen (ISO/DIS 18113-1:2021)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 1: Termes, définitions et exigences générales (ISO/DIS 18113-1:2021)

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

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

ICS:

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

oSIST prEN ISO 18113-1:2021 **en,fr,de**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

oSIST prEN ISO 18113-1:2021

iTeh STANDARD PREVIEW
(standards.iteh.ai)

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

oSIST prEN ISO 18113-1:2021

DRAFT INTERNATIONAL STANDARD

ISO/DIS 18113-1

ISO/TC **212**

Secretariat: **ANSI**

Voting begins on:
2021-08-02

Voting terminates on:
2021-10-25

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

Part 1:
Terms, definitions, and general requirements

ICS: 11.100.10

iTeh STANDARD PREVIEW
(standards.iteh.ai)

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 18113-1:2021(E)

© ISO 2021

oSIST prEN ISO 18113-1:2021

iTeh STANDARD PREVIEW
(standards.iteh.ai)

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

© ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)
oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

© ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

This document was prepared by Technical Committee TC212, *Clinical laboratory testing and in vitro diagnostic test systems.*

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2bee47dbe267/osist-pren-iso-18113-1-2021

This second edition cancels and replaces the first edition (ISO 18113-1:2009), which has been technically revised.

The main changes compared to the previous edition 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 European Union and other regulations

— Added additional detail for clarification

In this document, the following verbal forms are used: — “shall” indicates a requirement; — “should” indicates a recommendation; — “may” indicates a permission; — “can” indicates a possibility or a capability. Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

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.

 © ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

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 could 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 [49]) 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 must be respected.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d0a267/osist-pren-iso-18113-1-2021

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 ISO 18113. While the terms and definitions in International Standards are preferred, the terms and definitions used in the information supplied by an IVD manufacturer shall be subject to the requirements of 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, a source indicates that the definition has been modified and gives the source. 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.

© ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

Common English dictionary definitions apply to non-defined concepts, such as apparatus, device, constituent, equipment, evaluation, instrument, magnitude, material, part, phenomenon, property, reaction, signal, substance and system.

In addition, guidelines for the terms and definitions that describe the performance characteristics of IVD medical devices are given in Annex A. This information is not repeated in the subsequent parts, so 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.

Parts 1, 2 and 3 of ISO 18113 are the International Standards necessary for IVD medical devices intended for medical laboratories and other professional uses; Parts 1, 4 and 5 of ISO 18113 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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

© ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

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

Part 1: Terms, definitions, and general requirements

1 Scope

This document defines concepts, establishes general principles, and specifies essential requirements for information supplied by the manufacturer of IVD medical devices.

This document does not address language requirements since that is the domain of national laws and regulations.

This document does not apply to:

a) IVD medical devices for performance evaluation (e.g. for investigational use only);

b) packaging list;

c) material safety data sheets / Safety Data Sheets;

d) marketing information (consistent with applicable legal requirements).

iTeh STANDARD PREVIEW
(standards.iteh.ai)
oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

2 Normative references

The following documents are referred to in the text in such a way that some or all 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 1000, *SI units and recommendations for the use of their multiples and of certain other units*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

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

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

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document and ISO 18113, Parts 2 – 5, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

© ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

3.1
accessory
article intended explicitly by its *manufacturer* (3.42) to be used together with an *IVD medical device* (3.33):

— to enable the *IVD medical device* (3.33) to achieve its intended purpose or;

— to augment or extend the capabilities of the *IVD medical device* (3.33) in the fulfilment of its intended purpose.

[SOURCE: IMDRF/UDI/WG/N7, FINAL:2013, 5, modified — "specifically" has been replaced with "explicitly", "a specific medical device" has been replaced with "an IVD medical device (3.33)", "the medical device (3.53)" has been replaced with "the *IVD medical device* (3.33)", and " or — to augment or extend the capabilities of the *IVD medical device* (3.33) in the fulfilment of its intended purpose" has been added.]

3.2
advisory notice
communication issued by an organization, subsequent to delivery of a *medical device* (3.52), to provide supplementary information and/or to advise what action should be taken in:

— the use of a *medical device* (3.53);

— the modification of a *medical device* (3.53);

— the return of a *medical device* (3.53), to its *manufacturer* (3.42);

— the destruction of a *medical device* (3.53).

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Note 1 to entry: Note to entry: Issue of an advisory notice can be required to comply with national or regional regulations.

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

[SOURCE: ISO 13485:2016, 3.1]

3.3
aid to diagnosis IVD medical devices
are used to provide additional information to assist in the determination or verification of a patient's clinical status. The assay is not the sole determinant

Note 1 to entry: Note to entry: The assay is not the sole determinant

[SOURCE: GHTF/SG5/N8:2012, Appendix Table 1, modified — "Aid to diagnosis tests" has been replaced with "aid to diagnosis *in vitro diagnostic medical devices* (3.53)".]

3.4
analyte
component represented in the name of a measurable quantity

EXAMPLE In "the type of quantity "mass of protein in 24-hour urine", "protein" is the analyte. In "amount of substance of glucose in plasma", "glucose" is the analyte . In both cases, the long phrase represents the *measurand* (3.45)

[SOURCE: ISO 17511:2020, definition 3.2]

3.5
authorized representative
any natural or legal person established within a country or jurisdiction who has received a written mandate from the *manufacturer* (3.42) to act on his behalf for specified tasks with regard to the latter's obligations under that country's or jurisdiction's legislation

Note 1 to entry: Note to entry: In the European Union, Directive 98/79/EC [51] and Regulation 2017/746/EU require the *manufacturer* (3.42) to designate an "authorized representative", established in the European Community if the *manufacturer* (3.42) is not located in the European Community

 © ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

[SOURCE: GHTF/SG1/NO55:2009, 5.2, modified – Note to entry has been added]

3.6
automatic identification and data capture (AIDC)
a technology used to automatically capture data. AIDC technologies include bar codes, data matrix, and *radio frequency identification (RFID)* (3.69)

Note 1 to entry: Note to entry: AIDC technologies include bar codes, data matrix, and *radio frequency identification (RFID)(3.69)*

[SOURCE: IMDRF/UDI WG/N7:2013, modified – "smart cards, biometrics" has been replaced with "data matrix"]

3.7
batch
lot
defined amount of material that is uniform in its properties and has been produced in one process or series of processes

Note 1 to entry: Note to entry: The material can be either starting material, intermediate material, or finished product

3.8
batch code
lot number
a set of numbers and/or letters that specifically identifies a *medical device* (3.53) or an *IVD medical device* (3.33) and permits its manufacturing, packaging, *labelling* (3.35) and distribution history to be traced

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Note 1 to entry: Note to entry: This can be referred to as the lot code, batch number, or batch code

[SOURCE: IMDRF/GRRP WG/N52 2019 [45], 3.20]

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

3.9
biological reference interval
reference interval
specified interval of the distribution of values taken from a *biological reference population* (3.10)

EXAMPLE The 95 % biological reference interval for sodium ion concentration values in serum from a population of healthy male and female adults is 135 mmol/l to 145 mmol/l.

Note 1 to entry: A reference interval is commonly defined as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases.

Note 2 to entry: A reference interval can depend upon the type of *primary samples* (3.65) and the *examination* (3.20) procedure used.

Note 3 to entry: In some cases, only one biological reference limit is important, for example an upper limit, "x", so that the corresponding biological reference interval would be less than or equal to "x".

Note 4 to entry: Terms such as "normal range", "normal values", and "clinical range" are ambiguous and therefore discouraged.

[SOURCE: ISO 15189, 3.4]

3.10
biological reference population
reference population
group of individuals in a well-defined state of health or disease

Note 1 to entry: When *biological reference intervals* (3.9) are provided by a *manufacturer* (3.42) in the instructions for use, laboratories using the *IVD medical device* (3.33) are responsible for verifying that the biological reference populations represent the populations serviced by the laboratories.

© ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

Note 2 to entry: A biological reference population can be a defined homogenous group of apparently healthy individuals or individuals with a specific medical condition. The concept allows for relating the reference interval to age, gender, and ethnicity of the reference population, as appropriate.

3.11
calibration
operation that, under specified conditions in a first step, establishes a relationship between the quantity values with *measurement* (3.46), uncertainties provided by *measurement standards* (A.3.36), and corresponding *measurement indications* (A.3.31) with associated *measurement* (3.46) uncertainties and, in a second step, uses this information to establish a relationship for obtaining a *measurement result* (3.50) from an indication

Note 1 to entry: Calibration permits either the assignment of values of the *measurands* (3.44) to the *measurement indications* (A.3.31) provided by the measuring instrument, or the determination of a correction with respect to the values provided by the measuring instrument.

Note 2 to entry: Calibration is sometimes confused with adjustment of a *measuring system* (A.3.40), often mistakenly called self-calibration, or with *calibration verification* (3.12).

[SOURCE: ISO/IEC Guide 99:2007 [8], 2.39, modified- NOTE 1 and NOTE 3 have been deleted and new Note 1 to entry has been added]

3.12
calibration verification
verification of calibration
confirmation that stated trueness claims for an IVD *measuring system* (A.3.40) are achieved

iTeh STANDARD PREVIEW

Note 1 to entry: Calibration verification requires *reference materials* (3.71) with assigned values at concentrations appropriate for the *intended use* (3.37).

(standards.iteh.ai)

Note 2 to entry: Calibration verification is sometimes confused with *calibration* (3.11), linearity, *verification* (3.92), or routine *control procedures* (3.16).

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

3.13
calibrator
measurement standard (A.3.36) used in the *calibration* (3.11) of an IVD instrument or system

[SOURCE: ISO/IEC Guide 99:2007, 5.12, modified- “calibration” has been replaced with the *calibration* (3.11) of an IVD instrument or system” and NOTE has been deleted.]

3.14
component
part of a finished, packaged, and labelled *IVD medical device* (3.33)

EXAMPLE Raw material, substance, piece, part, software, firmware, *labelling* (3.35) or assembly

Note 1 to entry: Note to entry: Typical *kit* (3.38) components include antibody solutions, buffer solutions, calibrators (3.13), and/or control materials

[SOURCE: U.S. Code of Federal Regulations Title 21:2019, Part 820.3, modified — “device” has been replaced with “*IVD medical device* (3.32)”, and Note to entry has been added.]

3.15
control material
substance, material, or article intended by its *manufacturer* (3.42) to be used to verify the *performance characteristics* (3.57) of an *IVD medical device* (3.33)

 © ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

3.16
control procedure
set of operations at the point of use, described specifically, intended to monitor the *performance characteristics* (3.57) of an *IVD medical device* (3.33) and fulfil requirements for quality

Note 1 to entry: Note to entry: Control procedures can be intended to monitor all or part of the IVD *examination* (3.21) process, from the collection of the *sample* (3.77) to reporting the result of the examination (3.21)

[SOURCE: ISO 15198:2004, 3.5, modified — "activities" has been replaced with "set of operations", "to monitor" has been replaced with" "described specifically, intended to monitor" and "the performance of an *IVD medical device* (3.53)" has been replaced with "the performance characteristics of an *IVD medical device* (3.53) and fulfil requirements for quality", NOTE 1 has been deleted, and new Note to entry has been added.]

3.17
determination of physiological state
a common test purpose or function for an in vitro diagnostic *medical device* (3.53) whereby the test is used to evaluate the physiological state of an individual for the purpose of identifying a human condition or characteristic

Note 1 to entry: Determination of physiological state is one of the common *examination* (3.21) purposes for *IVD medical devices* (3.33).

Note 2 to entry: Physiological status determination tests are designed to evaluate a patient's current state.

[SOURCE: GHTF/SG5/N8:2012, Added definition, added Note 1 and Note 2 to entry from Table 1]

iTeh STANDARD PREVIEW
(standards.iteh.ai)

3.18
device identifier (UDI-DI)
a unique numeric or alphanumeric code specific to a model of *medical device* (3.53) and that is also used as the "access key" to information stored in a UDID. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-LIC (Labeller Identification Code)

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4a1e0e2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

EXAMPLE Include GS1 GTIN (Global Trade Item Number), HIBC-LIC (Labeler Identification Code)

Note 1 to entry: *Determination of physiological state* (3.17) is one of the common test purposes for *IVD medical devices* (3.33).

Note 2 to entry: Physiological status determination tests are designed to evaluate a patient's current state.

[SOURCE: IMDRF/UDI WG/N7:2013, 5 modified – ISBT 128-PPIC is not included in the list of examples. Note 1 and Note 2 to entry have been added.

3.19
diagnostic IVD medical device
are used to determine, verify, or confirm a patient's clinical condition as a sole determinant. This type of *examination* (3.21) also includes sole confirmatory assays (to verify the results of previous testing) and sole exclusion assays (to rule out a particular condition). Specimen receptacles are also considered as in vitro diagnostic medical devices

[SOURCE: GHTF/SG5/N8:2012 [43] *Clinical Performance Studies for in vitro diagnostic medical device* modified – term *examination* (3.21) replaces the word testing. Clarification added that specimen receptacles are in vitro diagnostic medical devices.]

3.20
distributor
any natural or legal person in the supply chain who, on his/her own behalf, furthers the availability of a *medical device* (3.53) to the end user

Note 1 to entry: More than one distributor can be involved in the supply chain.

© ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the *manufacturer* (3.42), *importer* (3.31), or distributor, are not distributors under this definition.

[SOURCE: GHTF/SG1/N055:2009 [44], 5.3]

3.21
examination
set of operations having the object of determining the value or characteristics of a property

Note 1 to entry: In some disciplines (e.g. microbiology) an examination is the total activity of a number of tests, observations or *measurements* (3.46).

Note 2 to entry: Laboratory examinations that determine the value of a property are called quantitative examinations; those that determine the characteristics of a property are called qualitative examinations.

Note 3 to entry: In clinical chemistry, laboratory examinations have been called assays or tests.

[SOURCE: ISO 15189:2012, 3.74]

3.22
expiry date
expiration date
upper limit of the time interval during which the *performance characteristics* (3.57) of a material stored under specified conditions can be assured

Note 1 to entry: Expiry dates are assigned to *IVD reagents* (3.34), *calibrators* (3.13), *control materials* (3.15), and other *components* (3.14) by the *manufacturer* (3.42), based on experimentally determined *stability* (3.85) properties.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Note 2 to entry: Guidelines for determining the *stability* (3.85) of *IVD medical devices* (3.33) are found in ISO 23640:2011.

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2dead7d6a267/osist-pren-iso-18113-1-2021

3.23
graphical symbol
visually perceptible figure used to transmit information independently of language

[SOURCE: ISO/IEC 80416-2:2008, 3.4]

3.24
harm
physical injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 63:2019, 3.1]

3.25
hazard
potential source of *harm* (3.24)

[SOURCE: ISO/IEC Guide 63:2019, 3.2]

3.26
hazardous situation
circumstance in which people, property or the environment are exposed to one or more *hazards* (3.25)

Note 1 to entry: Note to entry: Incorrect IVD *examination* (3.21) results can contribute to a hazardous situation for a patient. See ISO 14971:2019, Annex C

[SOURCE: ISO/IEC Guide 63:2019, 3.3, modified- Note to entry has been added]

 © ISO 2021 – All rights reserved

oSIST prEN ISO 18113-1:2021

3.27
hazardous waste
waste that is potentially harmful to human beings, property, or the environment

EXAMPLE Used reagent strips contaminated with human blood; reagent solution containing sodium azide; decommissioned instruments containing heavy metals.

Note 1 to entry: Note to entry: Includes waste that is flammable, combustible, ignitable, corrosive, toxic, reactive, injurious or infectious

[SOURCE: ISO 15190:2020, 3.14, modified- "flammable, combustible, ignitable, corrosive, toxic, reactive, injurious or infectious has been replaced with "harmful to human beings, property", and example and Note to entry has been added.]

3.28
healthcare provider
individual authorized to deliver health services to a patient

EXAMPLE Physician, nurse, ambulance attendant, dentist, diabetes educator, laboratory technician, medical assistant, medical specialist, respiratory care practitioner

3.29
Human Readable Interpretation (HRI)
legible interpretation of the data characters encoded in the *UDI carrier* (3.88)[SOURCE IMDRF/UDI/WG/N7 Final: 2013 [42]

3.30
immediate container
primary container
packaging that protects the contents from contamination and other effects of the external environment

iTeh STANDARD PREVIEW
(standards.iteh.ai)

EXAMPLE Sealed vial, ampoule or bottle, foil pouch, sealed plastic bag

oSIST prEN ISO 18113-1:2021
https://standards.iteh.ai/catalog/standards/sist/4d16fe2c-d79c-427c-98fc-2abad7d6a267/osist-pren-iso-18113-1-2021

Note 1 to entry: Note to entry: Does not include package liners

3.31
importer
any natural or legal person who is the first in a supply chain to make a *medical device* (3.53), manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed

Note 1 to entry: Note to entry: Importers are not permitted to repackage the goods or change their container, packaging, or *labelling* (3.35) in some jurisdictions, including the USA

[SOURCE: GHTF/SG1/N055:2009 [44], 5.4, modified – Note to entry has been added]

3.32
in vitro diagnostic instrument
IVD instrument
equipment or apparatus intended by a *manufacturer* (3.42) to be used as an *IVD medical device* (3.33)

3.33
in vitro diagnostic (IVD) medical device
IVD medical device
medical device (3.53), whether used alone or in combination, intended by the *manufacturer* (3.42) for the in vitro *examination* (3.21) of *specimens* (3.65) derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes

Note 1 to entry: *IVD medical devices* (3.33) include reagents, *calibrators* (3.13), *control materials* (3.15), *specimen* (3.65) receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, *predisposition* (3.62), prognosis, prediction, *determination of physiological state* (3.17).

© ISO 2021 – All rights reserved