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)

COPYRIGHT PROTECTED DOCUMENT

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.

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) shipping documents;

c) material safety data sheets / Safety Data Sheets;

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

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 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 information to be supplied by the manufacturer — 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, the following terms and definitions apply.

ISO and IEC maintain terminology 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/

3.1 General terms and definitions for use with in vitro diagnostic medical devices

3.1.1
accessory
article intended explicitly by its *manufacturer* (3.1.42) to be used together with an *IVD medical device* (3.1.33):

— to enable the *IVD medical device* (3.1.33) to achieve its intended purpose; or

— to augment or extend the capabilities of the *IVD medical device* (3.1.33) in the fulfilment of its intended purpose

Note 1 to entry: Adapted from IMDRF/UDI/WG/N7, FINAL:2013, 5.

3.1.2
advisory notice
communication issued by an organization, subsequent to delivery of a *medical device* (3.1.53), to provide supplementary information and/or to advise what action should be taken in:

— the use of a *medical device* (3.1.53);

— the modification of a *medical device* (3.1.53);

— the return of a *medical device* (3.1.53) to the *manufacturer* (3.1.42);

— the destruction of a *medical device* (3.1.53)

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

[SOURCE: ISO 13485:2016, 3.1, modified — “notice” has been replaced with “communication”, “or” has been replaced with “and/or”, “return of the medical device to the organization that supplied it” has been replaced with “return of the medical device to the manufacturer, ”]

3.1.3
aid to diagnosis IVD medical device
device used to provide additional information to assist in the determination or verification of a patient's clinical status

Note 1 to entry: The device is not the sole determinant.

[SOURCE: GHTF/SG5/N8:2012, Appendix Table 1, modified — “tests” has been replaced with “device” in the definition and Note 1 to entry.]

3.1.4
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* (3.1.45)

[SOURCE: ISO 17511:2020, 3.1]

3.1.5
authorized representative
any natural or legal person established within a country or jurisdiction who has received a written mandate from the *manufacturer* (3.1.42) to act on its behalf for specified tasks with regard to the latter's obligations under that country's or jurisdiction's legislation

Note 1 to entry: In the European Union, Directive 98/79/EC[54] and Regulation 2017/746/EU require the *manufacturer* (3.1.42) to designate an “authorized representative”, established in the European Community if the *manufacturer* (3.1.42) is not located in the European Community.

[SOURCE: GHTF/SG1/NO55:2009, 5.2, modified — Note 1 to entry has been added.]

3.1.6
automatic identification and data capture
AIDC
technology used to automatically capture data

Note 1 to entry: AIDC technologies include bar codes, data matrix, and *radio frequency identification (RFID)* (3.1.69).

[SOURCE: IMDRF/UDI WG/N7:2013, Clause 5, modified — "smart cards, biometrics" has been replaced with "data matrix".]

3.1.7
batch
lot
specified amount of material that is uniform in its properties and has been produced in one process or series of processes

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

3.1.8
batch code
batch number
lot number
set of numbers and/or letters that specifically identifies a *medical device* (3.1.53) or an *IVD medical device* (3.1.33) and permits its manufacturing, packaging, *labelling* (3.1.35) and distribution history to be traced

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

[SOURCE: IMDRF/GRRP WG/N52 2019,[52] 3.20]

3.1.9
biological reference interval
reference interval
specified interval of the distribution of values taken from a *biological reference population* (3.1.10)

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* (3.1.65) and the *examination* (3.1.21) 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 15189:2012, 3.4]

3.1.10
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* (3.1.9) are provided by a *manufacturer* (3.1.42) in the instructions for use, laboratories using the *IVD medical device* (3.1.33) are responsible for verifying that the biological reference populations represent the populations serviced by the laboratories.

Note 2 to entry: A biological reference population can be a specified 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.

3.1.11
calibration
operation that, under specified conditions, in a first step, establishes a relationship between the quantity values with *measurement* (3.1.46), uncertainties provided by *measurement standards* (3.2.36), and corresponding *measurement indications* (3.2.31) with associated *measurement* (3.1.46) uncertainties and, in a second step, uses this information to establish a relationship for obtaining a *measurement result* (3.1.51) from an indication

Note 1 to entry: Calibration permits either the assignment of values of the *measurands* (3.1.44) to the *measurement indications* (3.2.31) 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* (3.2.40), often mistakenly called self-calibration, or with *calibration verification* (3.1.12).

[SOURCE: ISO/IEC Guide 99:2007,[27] 2.39, modified — Notes 1 and 3 to entry have been deleted and new Note 1 to entry has been added]

3.1.12
calibration verification
verification of calibration
confirmation that stated trueness claims for an *IVD measuring system* (3.2.40) are achieved

Note 1 to entry: Calibration verification requires *reference materials* (3.1.71) with assigned values at concentrations appropriate for the *intended use* (3.1.37).

Note 2 to entry: Calibration verification is sometimes confused with *calibration* (3.1.11), linearity, *verification* (3.1.92), or routine *control procedures* (3.1.16).

3.1.13
calibrator
measurement standard (3.2.36) used in the *calibration* (3.1.11) of an IVD instrument or system

[SOURCE: ISO/IEC Guide 99:2007, 5.12, modified — “calibration” has been replaced with "calibration of an IVD instrument or system” and Note 1 to entryhas been deleted.]

3.1.14
component
part of a finished, packaged, and labelled *IVD medical device* (3.1.33)

EXAMPLE Raw material, substance, piece, part, software, firmware, *labelling* (3.1.35) or assembly.

Note 1 to entry: Typical *kit* (3.1.38) components include antibody solutions, buffer solutions, *calibrators* (3.1.13), and/or control materials.

[SOURCE: Reference [59], c), modified — “device” has been replaced with “IVD medical device (3.1.33)”, and Note 1 to entry has been added.]

3.1.15
control material
substance, material, or article intended by its *manufacturer* (3.1.42) to be used to verify the *performance characteristics* (3.1.57) of an *IVD medical device* (3.1.33)

3.1.16
control procedure
set of operations at the point of use, described specifically, intended to monitor the *performance characteristics* (3.1.57) of an *IVD medical device* (3.1.33) and fulfil requirements for quality

Note 1 to entry: Control procedures can be intended to monitor all or part of the IVD *examination* (3.1.21) process, from the collection of the *sample* (3.1.77) to reporting the result of the *examination* (3.1.21).

Note 2 to entry: Adapted from ISO 15198:2004, 3.5.

3.1.17
determination of physiological state
common test purpose or function for an *in vitro diagnostic medical device* (3.1.33) 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* (3.1.21) purposes for *IVD medical devices* (3.1.33).

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

Note 3 to entry: Adapted from GHTF/SG5/N8:2012,[46] Appendix Table 1.

3.1.18
device identifier
unique device identifier-device identifier
UDI-DI
unique numeric or alphanumeric code specific to a model of *medical device* (3.1.53) and that is also used as the “access key” to information stored in a unique device identifier-device identifier (UDI-DI)

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

[SOURCE: IMDRF/UDI WG/N7:2013, Clause 5 modified — ISBT 128-PPIC is not included in the list of examples.]

3.1.19
diagnostic IVD medical device
device used to determine, verify, or confirm a patient’s clinical condition as a sole determinant

Note 1 to entry: This type of *examination* (3.1.21) 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[46] modified — Term "examination" replaces the word ”testing". Clarification added that specimen receptacles are in vitro diagnostic medical devices.]

3.1.20
distributor
any natural or legal person in the supply chain who, on his or her own behalf, furthers the availability of a *medical device* (3.1.53) to the end user

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

Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the *manufacturer* (3.1.42), *importer* (3.1.31), or distributor, are not distributors under this definition.

[SOURCE: GHTF/SG1/N055:2009,[47] 5.3]

3.1.21
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* (3.1.46).

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, 3.7]

3.1.22
expiry date
expiration date
upper limit of the time interval during which the *performance characteristics* (3.1.57) of a material stored under specified conditions can be assured

Note 1 to entry: Expiry dates are assigned to *IVD reagents* (3.1.34), *calibrators* (3.1.13), *control materials* (3.1.15), and other *components* (3.1.14) by the *manufacturer* (3.1.42), based on experimentally determined *stability* (3.1.85) properties.

Note 2 to entry: Guidelines for determining the *stability* (3.1.85) of *IVD medical devices* (3.1.33) are found in ISO 23640:2011.

3.1.23
graphical symbol
visually perceptible figure with a particular meaning used to transmit information independently of language

[SOURCE: ISO/IEC 80416-1:2008, 3.4]

3.1.24
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, modified — Added 'physical' as first word in definition.]

3.1.25
hazard
potential source of *harm* (3.1.24)

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

3.1.26
hazardous situation
circumstance in which people, property or the environment are exposed to one or more *hazards* (3.1.25)

Note 1 to entry: Incorrect IVD *examination* (3.1.21) results can contribute to a hazardous situation for a patient. See ISO 14971, Annex C.

[SOURCE: ISO/IEC Guide 63:2019, 3.3, modified — Note 1 to entry has been added.]

3.1.27
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: 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 1 to entry have been added.]

3.1.28
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.

3.1.29
human readable interpretation
HRI
legible interpretation of the data characters encoded in the *unique device identifer carrier* (3.1.88)

[SOURCE: IMDRF/UDI/ WG/N7 Final: 2013,[50] Clause 5]

3.1.30
immediate container
primary container
packaging that protects the contents from contamination and other effects of the external environment

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

Note 1 to entry: Does not include package liners.

3.1.31
importer
any natural or legal person who is the first in a supply chain to make a *medical device* (3.1.53), manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed

Note 1 to entry: Importers are not permitted to repackage the goods or change their container, packaging, or *labelling* (3.1.35) in some jurisdictions.

[SOURCE: GHTF/SG1/N055:2009,[47] 5.4, modified — Note 1 to entry has been added.]

3.1.32
in vitro diagnostic instrument
IVD instrument
equipment or apparatus intended by a *manufacturer* (3.1.42) to be used as an *IVD medical device* (3.1.33)

3.1.33
in vitro diagnostic medical device
IVD medical device
medical device (3.1.53), whether used alone or in combination, intended by the *manufacturer* (3.1.42) for the in vitro *examination* (3.1.21) of *specimens* (3.1.65) derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes

Note 1 to entry: *IVD medical devices* (3.1.33) include reagents, *calibrators* (3.1.13), *control materials* (3.1.15), *specimen* (3.1.65) 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* (3.1.62), prognosis, prediction, *determination of physiological state* (3.1.17).

Note 2 to entry: In some jurisdictions, certain *IVD medical devices* (3.1.33) can be covered by other regulations.

[SOURCE: IMDRF GRRP WG/N52,[52] 3.18]

3.1.34
in vitro diagnostic reagent
IVD reagent
chemical, biological, or immunological components, solutions or preparations intended by the manufacturer to be used as an *IVD medical device* (3.1.33)

3.1.35
information supplied by the manufacturer
labelling
label (3.1.39), *instructions for use* (3.1.36), and any other information that is related to identification, technical description, *intended purpose* (3.1.37) and proper use of the *medical device* (3.1.53), but excluding shipping documents

EXAMPLE Labels, instructions for use, manual.

Note 1 to entry: *Labelling* (3.1.35) can also be referred to as "information supplied by the manufacturer".

Note 2 to entry: *Labelling* (3.1.35) can be in printed or electronic format and may either physically accompany the *medical device* (3.1.53) or direct the user to where the *labelling* (3.1.35) information can be accessed (such as through a website), as permitted by the applicable regulatory jurisdiction.

Note 3 to entry: In IEC standards, documents provided with a *medical device* (3.1.53) and containing important information for the responsible organization or operator, particularly regarding *safety* (3.1.76), are called "accompanying documents".

Note 4 to entry: Catalogues and material *safety* (3.1.76) data sheets are not considered *labelling* (3.1.35) of *IVD medical devices* (3.1.33).

[SOURCE: IMDRF/GRRP WG/N52 final 2019,[52] 3.18, modified — Title of term "information supplied by the manufacturer" has been added; Notes 3 and 4 to entry have been added.]

3.1.36
instructions for use
general and technical information provided by the *manufacturer* (3.1.42) to inform the user of a device's *intended purpose* (3.1.37) and proper use and of any contraindications, *warnings* (3.1.93) or *precautions* (3.1.64) to be taken

Note 1 to entry: It is provided by the *manufacturer* (3.1.42) to support and assist the device users in its safe and appropriate use.

Note 2 to entry: Includes the directions supplied by the *manufacturer* (3.1.42) for the use, maintenance, troubleshooting and disposal of an *IVD medical device* (3.1.33), as well as *warnings* (3.1.93) and *precautions* (3.1.64).

Note 3 to entry: Instructions for use can also be referred to as 'package insert' or manual for instruments.

[SOURCE: IMDRF/GRRP WG/N52 FINAL:2019,[52] 3.15, modified — Note 2 to entry has been added.]

3.1.37
intended use
intended purpose
objective intent of an IVD *manufacturer* (3.1.42) regarding the use of a product, process or service as reflected in the specifications, instructions and information supplied by the IVD *manufacturer* (3.1.42)

Note 1 to entry: Intended use statements for IVD *labelling* (3.1.35) can include two components: a description of the functionality of the *IVD medical device* (3.1.33) (e.g. an immunochemical *measurement procedure* (3.1.50) for the detection of *analyte* (3.1.4) "x" in serum or plasma), and a statement of the intended medical use of the *examination* (3.1.21) results.

Note 2 to entry: The intended use can include the indications for use.

[SOURCE: GHTF SG1/N77:2012,[48] 4.0, modified — "the manufacturer" has been replaced with "an IVD manufacturer" and "provided by the manufacturer" has been replaced with "supplied by the IVD manufacturer".]

3.1.38
kit
set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic *examination* (3.1.21), or a part thereof

Note 1 to entry: Kit components can include reagents (e.g. antibodies, enzymes, buffer, and diluents), calibrators, controls and other articles and materials.

[SOURCE: European Union Regulation 2017/746[54] Article 2, modified — Note 1 to entry has been added.]

3.1.39
label
written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices

Note 1 to entry: A label permanently affixed to an IVD instrument is considered *marking* (3.1.43).

[SOURCE: European Union Regulation 2017/746[54] – Article 2, modified — Note to entry has been added.]

3.1.40
lay person
lay user
individual who does not have formal education in a relevant field of healthcare or medical discipline

EXAMPLE Person who performs *self-testing* (3.1.79) without having a medical education.

Note 1 to entry: Principles for lay person(s) may also apply to *self-testing* (3.1.79) for an *IVD medical device* (3.1.33).

Note 2 to entry: For an *IVD medical device* (3.1.33) for self-collection or *self-testing* (3.1.79), a self-collector or self-tester is considered a lay user.

[SOURCE: IMDRF/GRRP/WG/N52,[52] 3.21, modified — The phrase " in a relevant field of healthcare or medical discipline" has been added, the EXAMPLE has been added, Note 1 to entry has been modified and Note 2 to entry was replaced by a new Note 2 to entry.]

3.1.41
limitation of the procedure
specific situation in which an IVD *examination* (3.1.21) procedure cannot perform as intended

Note 1 to entry: Factors that affect the performance of an IVD *examination* (3.1.21) procedure can be physiological as well as analytical.

3.1.42
manufacturer
any natural or legal person with responsibility for design and/or manufacture of a *medical device* (3.1.53) with the intention of making the *medical device* (3.1.53) available for use, under that person's name; whether or not such a *medical device* (3.1.53) is designed and/or manufactured by that person or on that person's behalf by another person(s)

Note 1 to entry: Provisions of national or regional regulations can apply to the definition of manufacturer.

Note 2 to entry: 'Design and/or manufacture', as referred to in the above definition, can include specification development, production, fabrication, assembly, processing, packaging, repackaging, *labelling* (3.1.35), *relabelling* (3.1.35), sterilization, installation, or remanufacturing of a *medical device* (3.1.53); or putting a collection of devices, and possibly other product, together for a medical purpose.