SLOVENSKI STANDARD
oSIST prEN ISO 17511:2019

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Diagnostični medicinski pripomočki in vitro - Zahteve za vzpostavitev meroslovne sledljivosti vrednosti, dodeljenih kalibratorjem, kontrolnim materialom in človeškim vzorcem (ISO/DIS 17511:2019)

In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO/DIS 17511:2019)

In-vitro-Diagnostika - Messung von Grössen in Proben biologischen Ursprungs - Metrologische Rückverfolgbarkeit von Werten, die Kalibratoren und Kontrollmaterialien zugeordnet sind (ISO/DIS 17511:2019)

Dispositifs médicaux de diagnostic in vitro - Mesurage des grandeurs dans des échantillons d'origine biologique - Traçabilité métrologique des valeurs attribuées aux agents d'étalonnage et aux matériaux de contrôle (ISO/DIS 17511:2019)

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11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

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In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

Dispositifs médicaux de diagnostic in vitro — Mesurage des grandeurs dans des échantillons d'origine biologique — Traçabilité métrologique des valeurs attribuées aux agents d'étalonnage et aux matériaux de contrôle

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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).

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For an explanation on 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 the following URL: 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*.

This second edition cancels and replaces the first edition (ISO 17511:2003), which has been technically revised. This new edition of ISO 17511 also cancels and replaces ISO 18153:2003, *In vitro diagnostic medical devices —Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials*, by way of incorporation of the special requirements for metrologically traceable calibration hierarchies for measurement of catalytic concentration of enzymes into this new edition. The main changes compared to the previous edition are as follows:

— inclusion of requirements for calibration hierarchies for catalytic concentration of enzymes (previously covered in ISO 18153:2003)

— to clarify that final reported values on human samples shall be metrologically traceable to the highest order available reference, the title and scope were modified to include metrological traceability of values assigned to human samples

— updated normative references to replace International Vocabulary of Basic and General Terms in Metrology, 2nd edition, ISO, Geneva (1993), with ISO/IEC Guide 99:2007,International vocabulary of metrology – Basic and general concepts and associated terms (VIM) and deleted ISO Guide 35:1989, Certification of reference materials - General and statistical principles

— revision of clause 4 to clearly define requirements of a manufacturer of an *in vitro* diagnostic medical device in establishing and documenting metrological traceability of assigned values (for calibrators, trueness controls and human samples), while incorporating requirements previously addressed in clauses 6, 7 and 8 (thus eliminating those sections)

— revision of clause 5 to incorporate additional models of metrologically traceable calibration hierarchies, especially subclause 5.3 for measurement of catalytic concentration of enzymes (previously addressed in ISO 18153:2003), and subclause 5.6 for an overview of the concept of metrological traceability to international harmonisation protocols (addressed in detail in ISO

21151, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for international harmonisation protocols establishing metrological traceability of values assigned to calibrators and human samples*)

Introduction

In laboratory medicine, the objective in examining a stated measurand in a human sample is to produce equivalent results within medically relevant limits, irrespective of the measurement procedure (MP) used or the laboratory performing the measurement. Equivalent results are important to support clinical practice guidelines that use laboratory results to assess risk for disease, and/or to diagnose or make treatment decisions for a medical condition. Equivalent results enable uniform application of medical decision limits and reference intervals in a way that will reduce errors due to inappropriate medical decisions and thus improve the quality of medical care for the people served by medical laboratories and other users of in vitro diagnostic medical devices (IVD MDs). Equivalent results are also important for analysing results in medical records for the purpose of supporting clinical decisions and conducting epidemiological investigations.

Equivalent results for human samples can be achieved by establishing traceability of the calibration of a MP to the highest available reference system component for a given measurand. Metrological traceability describes the calibration hierarchy and the sequence of value assignments, demonstrating an unbroken linkage between the measurement result for a human sample up to the highest available reference system component in the calibration hierarchy. The point at which metrological traceability begins (i.e. the highest level of metrological traceability in the calibration hierarchy) depends on the availability of higher order reference measurement procedures (RMPs), reference materials (RMs) or harmonisation protocols for the stated measurand.

Limitations in implementing metrologically traceable calibrations occur when different IVD MDs intended for the same measurand do not measure the same or very closely related measureable quantities. Some measurands of medical interest may be well-defined elements or molecules. Other measurands are complex and possibly variable mixtures of molecular species with medically relevant properties in common, but with differences in chemical structures and molecular complexes in varying proportions, e.g. glycoproteins with multiple isoforms, variant amino acid sequences, molecular complexes. When the selectivity of an IVD MD is inadequate, sample-specific influence quantities in human samples due to factors including disease, drugs or other pathological conditions may lead to erroneous values for the intended measured quantity. Thus, the selectivity of MPs at all levels in the calibration hierarchy for an IVD MD can influence the ability of a metrologically traceable calibration, even with traceability to higher order reference system components, to achieve equivalent results for human samples among different IVD MDs. Since measured values for complex molecular species are important for medical decisions, calibration hierarchies for IVD MDs, regardless of the molecular complexity of the measurand, need to be established with careful consideration and recognition of MP selectivity limitations. To help ensure that metrologically traceable calibrations for IVD MDs with claims of traceability to the same higher order reference system components are of practical value, the selectivity of the applicable IVD MDs shall be fit-for-purpose to achieve equivalent results for human samples among different IVD MDs.

This international standard presents requirements for documenting the calibration hierarchy for a measured quantity in human samples using a specified IVD MD up to the highest available metrological reference. This international standard includes models offering potential technical solutions to support metrological traceability of measured values for measurands in human samples, calibrators and trueness control materials.

In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

1 Scope

This international standard specifies technical requirements and documentation necessary to establish metrological traceability of values assigned to calibrators, trueness control materials and human samples for quantities measured by IVD MDs. The human samples are those intended to be measured, as specified for each IVD MD. Metrological traceability of values for quantities in human samples extends to the highest available reference system component, ideally to RMPs and certified reference materials (CRMs).

All parties having a role in any of the steps described in a calibration hierarchy for an IVD MD are subject to the requirements described. These parties include but are not limited to manufacturers (of IVD MDs), RMP developers (see ISO 15193), RM producers (see ISO 15194), and reference/calibration laboratories (see ISO 15195) supporting calibration hierarchies for IVD MDs.

NOTE Producers of RMs intended for use in standardization or calibration of IVD MDs include commercial and non-commercial organizations producing RMs for use by many end-users of IVD MDs and/or calibration laboratories, or for use by a single end-user medical laboratory, as in the case of a measurement standard (calibrator) intended to be used exclusively for calibration of a laboratory-developed MP.

This international standard is applicable to:

a) all IVD MDs that provide measurement results in the form of numeric values, i.e. rational (ratio) and/or differential (interval) scales, and counting scales

b) IVD MDs where the measurement result is reported as a qualitative value established with a ratio of two measurements (i.e. the signal from a specimen being tested and the signal from a RM with a specified concentration or activity at the cut-off), or a counting scale, with corresponding decision threshold(s). This also includes IVD MDs where results are categorized among ordinal categories based on pre-established quantitative intervals for a quantity.

c) RMs intended for use as trueness control materials for verification or assessment of calibration of IVD MDs, i.e. some commutable CRMs and some external quality assessment (EQA) materials (if so indicated in the RM's intended use statement)

d) IVD MD-specific calibrators and trueness control materials with assigned values, intended to be used together with a specified IVD MD.

e) IVD MDs as described in a) and b), where no end-user performed calibration is required (i.e. when the manufacturer performs a factory calibration of the IVD MD).

This international standard is not applicable to:

a) calibrators and trueness control materials for IVD MDs which, due to their formulation, are known to have zero amount of measurand.

b) control materials that are used only for internal quality control purposes in medical laboratories to assess the imprecision of an IVD MD, either its repeatability or reproducibility, and/or for assessing changes in IVD MD results compared to a previously established calibration condition;

c) control materials that are used only for internal quality control purposes in medical laboratories and which are supplied with intervals of suggested acceptable values that are not metrologically traceable to higher order reference system components;

d) properties reported as nominal scales and ordinal scales, where no magnitude is involved

NOTE 1 Nominal scales are typically used to report e.g. identity of blood cell types, microorganism types, identity of nucleic acid sequences, identity of urine particles.

NOTE 2 Ordinal scales are often applied to results differentiated into dichotomous groupings (e.g. 'sick' vs. 'healthy'), and may also be applied to results differentiated into non-dichotomous categories where the result categories are rank-ordered but the rank-ordered categories cannot be differentiated in terms of relative degree of difference, e.g. negative, +1, +2, +3 for grading of presence of haemoglobin in urine specimens by visual observation.

2 Normative references

The following document is 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/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
analyte
component represented in the name of a measurand
constituent of a sample with a measureable property

EXAMPLE In the measurand (measured quantity) "mass of total protein in 24-hour urine", "total protein" is the analyte (and "mass" is the property.) In "amount of substance concentration of glucose in plasma", "glucose" is the analyte (and "amount of substance concentration" is the property.)

[SOURCE: Adapted from ISO 18113-1:2009]

3.2
analytical selectivity
selectivity of a measuring system
selectivity
property of a measuring system, used with a specified MP, whereby it provides measured quantity values for one or more measurands such that the values of each measurand are independent of other measurands or other quantities in the phenomenon, body, or substance being investigated

EXAMPLE Capability of a measuring system to measure the amount-of-substance concentration of creatinine in blood plasma without being influenced by the other components present in the sample.

Note 1 to entry: In chemistry, selectivity of a measuring system is usually obtained for quantities with selected components in concentrations within stated intervals.

Note 2 to entry: Selectivity as used in physics is a concept close to specificity as it is sometimes used in chemistry.

[SOURCE: Adapted from VIM, 4.13]

3.3
measurement bias
bias
estimate of a systematic measurement error

[SOURCE: VIM, 2.18]

Note 1 to entry: See VIM, 2.17, systematic measurement error

Note 2 to entry: This definition of applies to quantitative measurements only.

3.4
calibration
operation that, under specified conditions, in a first step, establishes a relation between the quantity values with associated measurement uncertainties provided by measurement standards (calibrators) and their corresponding indications and, in a second step, uses this relationship to establish a measurement result from an indication (for an unknown sample).

Note 1 to entry: A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

Note 2 to entry: Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, or with verification of calibration.

Note 3 to entry: Often, the first step alone in the above definition is perceived as being calibration.

[SOURCE: Adapted from VIM, 2.39]

3.5
calibration hierarchy
sequence of calibrations from a reference to the final measuring system, where the outcome of each calibration depends on the outcome of the previous calibration.

Note 1 to entry: Measurement uncertainty necessarily increases along the sequence of calibrations.

Note 2 to entry: The elements of a calibration hierarchy are one or more measurement standards and measuring systems operated according to MPs.

Note 3 to entry: A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

[SOURCE: VIM, 2.40]

Note 4 to entry: In this document, a calibration hierarchy is defined as a detailed description of the process for assigning a value of a measurand to a sample using a specified sequence of MPs and RMs (calibrated by higher order RMs and/or MPs for the same type of quantity, where available.)

Note 5 to entry: For purposes of this definition, a sample includes human samples as well as calibration materials, EQA materials or other RMs.

3.6
calibrator
measurement standard used in calibration

[SOURCE: VIM, 5.12]

Note 1 to entry: In this international standard, calibrator is synonymous with calibration material.

Note 2 to entry: A calibrator is a measurement standard used in the calibration of a measuring system according to a specified MP.

3.7
catalytic activity
property of a component corresponding to the catalysed substance rate of conversion of a specified chemical reaction, in a specified measurement system

[SOURCE: Adapted from (26)]

Note 1 to entry: In this standard the "component" is an enzyme.

Note 2 to entry: The quantity "catalytic activity" relates to an amount of active enzyme, not its concentration, see subclause 3.8.

Note 3 to entry: The coherent derived SI unit is "katal" (kat), equal to "mole per second" ($mol\ s^{-1}$).

Note 4 to entry: The MP is an essential element of the definition of the measurand for the quantity "catalytic activity".

Note 5 to entry: In many instances, instead of the conversion rate of the substrate ascribed in the short name of the enzyme analyte, e.g. "creatine" in "creatine kinase", the conversion rate of an indicator substance as substrate of a combined reaction is measured. (In these circumstances) the measurand should be defined as 'catalytic activity of the enzyme as measured by the conversion rate of an indicator substance in a specified system according to a given MP', e.g. 'catalytic activity of creatine kinase as measured by the rate of conversion of NADP+ in the IFCC reference procedure in human serum'.

[SOURCE: Adapted from ISO 18153:2003, 3.2]

3.8
catalytic-activity concentration
catalytic concentration
catalytic activity of a component divided by volume of the original system[SOURCE: Adapted from [26]]

Note 1 to entry: The coherent derived SI unit is "katal per cubic metre" or "mole per second cubic metre" ($kat\ m^{-3}$ = $mol\ s^{-1}\ m^{-3}$). In laboratory medicine, the unit of volume can be chosen to be "litre" (L).

Note 2 to entry: In this standard the "component" is an enzyme and the "original system" can be, for example, blood plasma.

[SOURCE: Adapted from ISO 18153:2003, 3.3]

3.9
certified reference material
CRM
RM accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures.

EXAMPLE Human serum with assigned quantity value for the concentration of cholesterol and associated measurement uncertainty stated in an accompanying certificate, used as a calibrator or measurement trueness control material.

Note 1 to entry: 'Documentation' is given in the form of a 'certificate' (see ISO Guide 31).

Note 2 to entry: Procedures for the production and certification of CRMs are given in ISO 17034:2016 and ISO Guide 35:2017.

Note 3 to entry: In this definition, "uncertainty" covers both 'measurement uncertainty' and 'uncertainty associated with the value of a nominal property', such as for identity and sequence. "Traceability" covers both 'metrological traceability of a quantity value' and 'traceability of a nominal property value'.

Note 4 to entry: Specified quantity values of CRMs require metrological traceability with associated measurement uncertainty[27].

Note 5 to entry: ISO/REMCO has an analogous definition[27] but uses the modifiers "metrological" and "metrologically" to refer to both quantities and nominal properties.

[SOURCE: Adapted from VIM, 5.14]

Note 6 to entry: Specific requirements for CRMs and the content of supporting documentation (in the field of in vitro diagnostic medical devices) are given in ISO 15194.

Note 7 to entry: For a specified material, a calibration certificate provided by an accredited calibration laboratory does not confer the status of CRM on these types of materials.

3.10
commutability of a reference material
property of a RM, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two MPs, and the relation obtained among the measurement results for other specified materials

Note 1 to entry: The RM in question is usually a calibrator and the other specified materials are usually routine samples.

[SOURCE: VIM, 5.15]

Note 2 to entry: It is typical that there are more than two MPs available and comparison among all applicable MPs is desirable.

Note 3 to entry: The requirement for the closeness of agreement shall be appropriate for the intended use of the RM.

Note 4 to entry: The commutability statement is restricted to the MPs as specified in a particular comparison.

3.11
control material

substance, material or article intended by its manufacturer to be used to verify performance characteristics of an IVD MD.

[SOURCE: Adapted from ISO 18113-1, 3.13]

3.12
end-user IVD MD calibrator
RM used as a measurement standard (calibrator) intended for use with one or more MPs intended to examine a particular measurand in human samples.

3.13
equivalence of measured values
equivalent results
agreement of measured values among different IVD MDs intended to measure the same measurand, where the differences in measured values on the same human samples do not affect clinical interpretation.[SOURCE: Adapted from Harmonization.net[28]]

Note 1 to entry: A conclusion of equivalence of measured values for the same human samples among two or more MPs should be based on the measured values being within a pre-defined margin or limit.

3.14
higher order reference material
a CRM that meets internationally accepted quality requirement and provides a common metrological reference within calibration hierarchies to which manufacturers can establish metrological traceability.

Note 1 to entry: Quality requirements for higher order RMs are laid out in ISO 15194.

Note 2 to entry: Higher order RMs include fit–for–purpose primary RMs, primary calibrators, secondary calibrators and international conventional RMs.

Note 3 to entry: Pure substances constitute the primary measurement standard and ultimate source of higher-order metrological traceability for most traceability chains in chemistry, thermometry and calorimetry in general and for the certification of solution and matrix RMs in particular (see ISO Guide 35:2017).

Note 4 to entry: VIM, clause 5.14 defines a CRM as a "reference material accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures."

Note 5 to entry: According to Joint Committee for Traceability in Laboratory Medicine (JCTLM) FAQs,[29] a higher order RM is a CRM, meeting internationally accepted quality requirements, to which other measurement results can be referenced, and its measurement uncertainty is completely established. Metrologically, a higher order RM is a RM deployed at a higher level in the calibration hierarchy. Certified, highest order RMs, where available, are used by IVD MD manufacturers to assign values to working calibrators. These working calibrators are subsequently used by the manufacturer to assign values to measurands in end-user IVD MD calibrators and control materials for use with IVD MDs in medical laboratories and other IVD testing environments. Higher order RMs are most commonly produced and distributed by national metrology institutes (NMIs), e.g. U.S. National Institute of Standards and Technology (NIST), European Commission Joint Research Centre (EU-JRC), LGC Standards (UK), World Health Organization (WHO), National Institute for Biological Standards and Control (UK), National Institute of Metrology (CN), National Metrology Institute of Japan (JP), Reference Material Institute for Clinical Chemistry Standards (JP), Japanese Industrial Standards Committee (JISC), Centro Nacional de Metrología (MX), etc. Some commercial sources also provide RMs listed by JCTLM[30].

3.15
higher order reference measurement procedure
higher order RMP
reference measurement procedure (RMP) meeting internationally accepted quality requirements and providing a common metrological reference within calibration hierarchies to which manufacturers' can establish metrological traceability and accepted as providing measurement results fit for their intended use in assessing measurement trueness

Note 1 to entry: Quality requirements for higher order RMPs are defined in ISO 15193.

Note 2 to entry: For reasons of higher cost, equipment complexity and operator training requirements, higher order RMPs are typically performed in national metrology institutes and/or accredited calibration laboratories.

Note 3 to entry: In laboratory medicine, RMPs that meet the requirements of ISO 15193 are considered to be higher order RMPs.

Note 4 to entry: According to JCTLM FAQs,[29] higher order reference (MPs) are well documented, high accuracy (MPs) used for assigning values to calibration materials. At the highest level (these MPs) are frequently expensive to develop, too complicated for routine use and not suitable for high throughput analysis.

3.16
influence quantity
quantity that, in a direct measurement, does not affect the quantity that is actually measured, but affects the relation between the indication and the measurement result

EXAMPLE amount-of-substance concentration of bilirubin in a direct measurement of hemoglobin amount-of-substance concentration in human blood plasma.

[SOURCE: VIM, 2.52]

3.17
international conventional calibrator
international conventional calibration material
calibrator whose quantity value is not metrologically traceable to the SI but is assigned by international agreement

Note 1 to entry: The quantity is defined with respect to the intended clinical application.

3.18
international conventional reference measurement procedure
international conventional RMP
MP yielding values that are not metrologically traceable to the SI but which by international agreement are used as reference values for a defined quantity

Note 1 to entry: The quantity is defined with respect to the intended clinical application.

3.19
international harmonisation protocol
description of a process implemented by an international body to achieve equivalence of measured values within medically acceptable limits among two or more IVD MDs intended for examination of the same measurand for cases where there are no higher order RMPs and no fit for purpose CRMs or international conventional calibrators

Note 1 to entry: A harmonisation protocol can be used to achieve standardization of measured values for a stated measurand when there are no other higher order reference system components that are suitable for use.

3.20
international measurement standard
international standard
measurement standard recognized by signatories to an international agreement and intended to serve worldwide (as the basis for assigning values to other standards for the same quantity)

EXAMPLE 1 The international prototype of the kilogram

[SOURCE: VIM, 5.2]

EXAMPLE 2 ERM®-DA470k/IFCC for the calibration of immunoassay-based in-vitro diagnostic devices or control products for the proteins certified. European Commission – Joint Research Centre (JRC), Geel, Belgium

EXAMPLE 3 Triple point of water - the single combination of pressure and temperature at which liquid water, solid ice, and water vapour coexist in a stable equilibrium, occurring at exactly 273.16 K (0.01 °C; 32.02 °F) at a partial vapour pressure of 611.657 pascals (6.11657 mbar; 0.00603659 atm)

3.21
***in vitro* diagnostic medical device (IVD MD)**
device which, whether used alone or in combination with other devices, is intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, measuring systems, software, and related instruments, apparatus or other articles.

[SOURCE: Adapted from GHTF/SG1/N045:2008]

3.22
manufacturer
Any entity* with responsibility for design and/or manufacture of an IVD MD with the intention of making the IVD MD available for use, under their name; whether or not such an IVD MD is designed and/or manufactured by that person themselves or on their behalf by another person(s).

* The term “entity” includes but is not limited to an individual, a corporation (or other legally established business), an association, an institution, or a medical laboratory. An entity should be identifiable in terms of a separate and distinct existence and objective reality.

Note 1 to entry: The manufacturer has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the IVD MD in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another entity by the Regulatory Authority (RA) within that jurisdiction.

Note 2 to entry: The manufacturer’s responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: ‘Design and/or manufacture’, as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of an IVD MD; or putting a collection of IVD MDs, and possibly other products, together for a medical purpose.