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Clinical laboratory testing and *in vitro* diagnostic test systems — *In vitro* diagnostic medical devices for professional use — Summary of regulatory requirements for information supplied by the manufacturer

Essais cliniques de laboratoire et systèmes d'essai de diagnostic in vitro — Dispositifs de diagnostic médical in vitro à usage professionnel — Résumé des exigences de régulation pour les informations fournies par le fabricant



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Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Labelling requirements	1
3 Commonalities in required information supplied by the manufacturer.....	2
4 Differences in required information supplied by the manufacturer	2
4.1 Definition of <i>in vitro</i> diagnostic medical device	2
4.2 Definitions of label and labelling.....	2
4.3 Instructions for use	3
4.4 Labelling media.....	3
4.5 Manufacturer, distributor, importer, exporter, authorized representative.....	3
4.6 Microbiological state	4
4.7 Language and country-specific requirements.....	4
4.8 Graphical symbols.....	4
4.9 Expiry date.....	4
4.10 Reactive ingredients.....	4
4.11 Small-sized label exemption.....	5
4.12 <i>In vitro</i> (diagnostic) use	5
4.13 Danger warnings (e.g. chemical, biological, radioactive hazards).....	5
4.14 Components of human or animal origin.....	5
4.15 Reagent preparation and storage	5
4.16 Units of measure.....	6
4.17 Analytical performance characteristics.....	6
4.18 Metrological traceability.....	6
4.19 Diagnostic performance characteristics	7
4.20 Predicate device (an existing legally marketed medical device)	7
4.21 Reference intervals.....	7
4.22 User quality control	7
4.23 Change notification	7
4.24 Limitations	7
4.25 Instrument requirements	8
Annex A (informative) Labelling requirements of countries surveyed.....	9
Bibliography	118

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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.

ISO/TR 18112 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Introduction

This Technical Report summarizes the current labelling requirements of Canada, the EU, Japan and the US for *in vitro* diagnostic (IVD) medical devices for professional use. It also includes, for comparison, proposed guidance from the Global Harmonization Task Force (GHTF) and recommendations from the *In vitro* Diagnostic Device Working Group of the Australian National Coordinating Committee for Therapeutic Goods. This technical report is intended for use in identifying gaps between existing CEN documents and country regulations, and the best solution for these gaps; it is one of a multi-part series of documents that is described in ISO/TC 212 New Work Item Proposal N96-Rev.1.

This summary provides regulatory authorities, manufacturers and users of IVD medical devices with an opportunity to compare existing and proposed labelling requirements from a cross-section of the regulated world, so significant differences can be recognized and addressed. A preliminary summary has been provided to the GHTF for use in identifying opportunities for harmonizing IVD labelling requirements. This report was prepared to assist ISO/TC 212 in developing international standards to support the harmonization efforts.

While significant benefits from harmonized labelling requirements are anticipated, this Technical Report does not evaluate the merits of one regulatory approach over another. Rather, it presents existing requirements factually, so organizations charged with developing harmonized regulations and standards can decide which requirements are essential for promoting safe and effective IVD medical devices.

This summary is only a snapshot in time, while the regulatory environment is dynamic and changing. Australia and Japan are developing new regulatory frameworks for IVD medical devices. The United States is revisiting its position on graphical symbols. European countries continue to debate which languages are necessary on limited label space.

Manufacturers are cautioned that this Technical Report does not substitute for official published labelling requirements. Although efforts were made to verify the accuracy of the information at this point in time, regulatory requirements are subject to interpretation and change. Specific guidance may be in place in some countries that interprets, explains, clarifies, amplifies or even modifies the requirements. Manufacturers are responsible for knowing, understanding and complying with the official regulatory requirements in each country in which their product is sold.

Document Reference: ISO TR 18112-2006

Clinical laboratory testing and *in vitro* diagnostic test systems — *In vitro* diagnostic medical devices for professional use — Summary of regulatory requirements for information supplied by the manufacturer

1 Scope

This Technical Report summarizes regulatory requirements and associated guidance for information supplied by the manufacturer with IVD medical devices intended for professional use.

Information supplied by the manufacturer includes labels on the outer and immediate container as well as instructions for use.

Current labelling regulations and regulatory guidance from Canada, the European Union, Japan and the United States are included.

Labelling guidance from the Global Harmonization Task Force and proposed labelling regulations from Australia are included for comparison.

IVD medical devices for self-testing are excluded.

2 Labelling requirements

EN 375:2001 and EN 591:2001 are harmonized European standards for reagents and instruments, respectively. These standards have been proposed as the basis for the international labelling standards being developed by TC 212, and therefore are used as the basis for comparison in this report.

The labelling requirements from the countries surveyed are presented in Annex A, which is organized in a table format to facilitate comparison of requirements and identification of key commonalities and differences. The source documents are listed in the Bibliography.

The first column in the table lists the requirements of EN 375 and EN 591 in approximately the order that they appear in the Standards. Subsequent columns present the corresponding regulatory requirements. Where a regulatory requirement was identified that did not correspond to a specific requirement in the standard, an additional row was entered at an appropriate place in the table.

For some topics, comparison may not be straightforward because the source documents are organized in different ways. The CEN standards are organized by location of the required information (i.e. outer packaging, inner packaging, accompanying documentation). Some regulations are organized by the type of information required; some specify where the information must be placed, while others allow the manufacturer to determine the most suitable location.

3 Commonalities in required information supplied by the manufacturer

The following information is required or allowed by all of the regulations and regulatory proposals surveyed:

- Device name.
- Batch code or serial number.
- Expiry date for reagents.
- Intended purpose or intended use.
- Specified storage conditions or environmental conditions.
- Container contents (e.g. mass, volume, number of tests) for reagents.
- Instructions for use, which must be supplied with the device, when required.
- Statement that the device is for *in vitro* use.
- Description of the test procedure.
- Calculation of results.
- Warnings, precautions, and limitations of the device.

Exemptions are allowed for immediate-container labels that cannot accommodate the entire list of required information.

4 Differences in required information supplied by the manufacturer

Requirements for the following topics differed significantly across the regulations surveyed.

4.1 Definition of *in vitro* diagnostic medical device

A harmonized definition of medical device, including *in vitro* diagnostic medical device, has been proposed by the GHTF, but has not yet been adopted by the participating countries.

The European Union, the United States and Canada consider calibrators and control materials to be IVD medical devices and must be labelled as such.

In Japan, IVD regulations do not apply to calibrators and control materials, unless they are part of a kit.

Accessories are IVD medical devices, according to EU definition, only when they are specifically intended for diagnostic use by their manufacturer.

4.2 Definitions of label and labelling

GHTF defines a label as information provided upon the medical device itself or on its packaging.

Australian, EU, Japanese and U.S. definitions and/or common usage are consistent with the GHTF definition.

The Canadian Food and Drugs Act defines label to include “any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package,” i.e. what GHTF and other countries inclusively term “labelling” and what the EU terms “information supplied by the manufacturer.”

4.3 Instructions for use

All countries require instructions for use unless the device can be used safely and effectively without them. Specific requirements differ in detail and flexibility.

GHTF guidance states that labelling content, format, and location should be appropriate to the device and its intended purpose, e.g. in a leaflet, packaging insert or other means supplied with one or multiple devices.

Australia and the U.S. also allow instructions for use to accompany the device, with “accompany” being interpreted liberally. The U.S. Federal Food, Drug and Cosmetic Act states that “accompanying” means more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. as well as labelling that is brought together with the device after shipment or delivery for shipment in interstate commerce.

Canadian Medical Devices Regulations state that directions for use are required, unless directions are not required to use the device safely and effectively. Draft guidance from Health Canada states that package inserts are essential for most IVDs.

The EU IVD Medical Device Directive states that instructions for use must accompany or be included in the packaging of one or more devices, except that in duly justified and exceptional cases instructions for use are not needed if the device can be used properly and safely without them. “Accompany” is not defined and has been interpreted differently by member states.

Japanese regulations require instructions for use with each device.

4.4 Labelling media

GHTF guidance states that instructions for use may be presented on a display screen incorporated into the device, via internet access to the manufacturer’s web site, or on magnetic or optical media, as well as printed documents, with the information targeted to the anticipated user population.

Current requirements and practices vary considerably.

Electronic labelling is not prohibited or otherwise mentioned in Australian, Canadian regulations, nor in the IVD Medical Device Directive.

The US authorizes, by statute, the use of electronic labelling, rather than the traditional paper labelling by distributors of prescription devices that are to be used within the confines of a health care facility, so long as they afford users the opportunity to request the labelling in paper form and promptly provide such labelling to requestors without additional cost.

The U.S. also permits manufacturers to provide instructions for IVD systems, including consumable reagents, in user manuals. Most countries have adopted similar policies regarding user manuals.

The EN labelling standards allow the use of separate manuals and alternative media (e.g. electronic labelling) for instructions for use.

Japan requires written instructions in hard-copy format, while a draft Guidance Document from Health Canada states that package inserts are essential for most IVDDs.

4.5 Manufacturer, distributor, importer, exporter, authorized representative

The U.S. requires that the name and place of business of manufacturer, packer, or distributor appear on the label for, or the labelling accompanying each product.

The EU IVD Medical Device Directive states the manufacturer is the legally responsible entity and requires the manufacturer’s name on the labels. If the manufacturer is outside the EU, its “Authorized Representative” must also be identified in the labelling.

Australia and Japan require the importer to be identified. Australia also requires the Australian exporter to be identified, if applicable.

Differences exist in the location where this information must be placed, e.g. outer package label and/or instructions for use.

4.6 Microbiological state

All regulations require a sterility designation for sterile products. The IVD Medical Device Directive requires an additional statement describing the microbiological state or state of cleanliness, where necessary for proper performance.

4.7 Language and country-specific requirements

The GHTF recommends that country-specific requirements and languages be limited to those essential for the safe and effective use of the device.

Australia and Japan require all information to be in English and Japanese, respectively.

Canada prefers both English and French, but accepts either one if a translation is readily available in the other language.

The EU allows each country to decide whether to require its national language, taking into account the principle of proportionality, whether harmonized symbols can be used, and the intended user. Some countries accept one of the major European languages as sufficient for professional use devices.

The United States requires English, except in its territories and the Commonwealth of Puerto Rico where the predominant language may be used. If any labelling appears in a foreign language, all of the required information must appear in that language.

4.8 Graphical symbols

The GHTF supports the use of internationally recognized symbols to replace wording on labels and labelling where the meaning is unambiguous.

Australia, Canada and the EU IVD Medical Device Directive are consistent with the GHTF position.

The U.S. and Japan presently require explanatory wording to appear in association with the symbol. However, a recent draft guidance document from FDA states that 25 symbols from ISO 15223 and EN 980 have been recognized as symbols that may be used on labels without explanatory wording for professional use devices.

4.9 Expiry date

The IVD Medical Device Directive requires the use of the ISO 8601 date format, i.e. CCYY-MM-DD.

Other countries allow any date format that is unambiguous.

As an alternative to an expiry date, the US allows the label to state an observable indication of stability or a simple method by which the user can confirm stability.

4.10 Reactive ingredients

The U.S. requires a list of reactive ingredients, as well as their concentrations, on the outer and immediate containers, and in the instructions for use. In the case that the immediate container is too small, the reactive ingredients may appear in the outer-container labelling only. Metric system units are encouraged.

In the EU and Canada, it is sufficient to list the reactive ingredients and their concentrations in the instructions for use.

Japan allows reactive ingredients and their concentrations to be listed in the instructions for use, but also requires the ingredient name on the outer container.

4.11 Small-sized label exemption

All countries allow for the possibility that the label space on small containers will not accommodate all of the required information. However, requirements vary as to what details on a small-sized label may be eliminated or placed elsewhere.

Furthermore, the US Food Drug and Cosmetic Act considers a product misbranded when any required information is omitted from a label if any of the label space is occupied by non-required information. Thus the small-label exemption does not apply if any information required by another country is on the label, such as a CE Mark or name of the authorized representative, unless it is also required by US law.

4.12 *In vitro* (diagnostic) use

Particular requirements vary. Some regulations allow use of a symbol to indicate the reagent is for *in vitro* diagnostic use. Others require specific wording. The EU specifies "*in vitro* use" as an alternative to the symbol. The U.S. and Canada specify "*in vitro* diagnostic use." The U.S. FDA has announced plans to accept the international IVD symbol.

4.13 Danger warnings (e.g. chemical, biological, radioactive hazards)

Particular requirements for warning users of hazardous substances vary from country to country.

In the EU, Directives on classification, packaging and labelling of dangerous substances and dangerous preparations require standardized symbols and specific risk and safety phrases in product labelling. Compliance with the labelling requirements of these Directives is mandated by the IVD Medical Device Directive.

In the U.S., compliance with the Federal Hazardous Substances Control Act is specifically required by the IVD labelling regulations. The manufacturer is additionally required to state other warnings appropriate to the hazard presented by the product. In Australia, Canada, the EU and the U.S., (Material) Safety Data Sheets may also be required unless all information required by occupational safety laws is included in the product labelling.

Canada and Japan require appropriate hazard warning phrases/statements or symbols. Japan requires specific language in a specific format for poisonous or powerful reagents.

NOTE This report does not attempt to include all danger/hazard warning requirements. Compulsory labelling requirements may also be found in other national and local regulations.

4.14 Components of human or animal origin

Disclosure of materials from human and animal sources is required by some countries, regardless of whether a hazard is known to exist. Compulsory labelling may also be required by worker protection regulations.

4.15 Reagent preparation and storage

The U.S. specifies that storage instructions for reconstituted or mixed product are required on the container label. If the label is too small, the storage instructions may be included in labelling accompanying the product.

In other countries, these instructions may be placed in the instructions for use.

4.16 Units of measure

The EU requires numerical values to be given in legal units, which means SI units of measure (ISO 1000).

The U.S. Food Drug and Cosmetic Act encourages the use of SI units for reagent ingredients. However, US IVD labelling regulations require quantity, proportion, concentration or activity to be stated in the system generally used and recognized by the intended user.

Australian, Canadian and Japanese labelling regulations are silent regarding units.

4.17 Analytical performance characteristics

All countries require a description of expected performance and provide examples of typical characteristics that might be included.

Significant differences exist in the definitions of some common performance characteristics, such as accuracy, precision, trueness, and sensitivity. Most of these terms are not defined in the labelling regulations, but may be defined in laboratory regulations or national standards that influence the terms used by manufacturers in labelling. It will be necessary to standardize these terms for labelling to be interpreted consistently worldwide.

Accuracy: In US laboratory regulations (CLIA '88) and in the EU IVD Medical Device Directive, accuracy is used to describe two different concepts: (1) agreement of the average of a large series of replicate measurements with the true value, and (2) agreement of an individual measurement result with the true value.

In international standards, including European harmonized standards, the first is termed "trueness," a measure of systematic bias; the second is termed "accuracy," which includes the effects of imprecision as well as bias on a test result. Many countries have adopted the terminology used in international standards.

Precision: In international standards, precision is described as repeatability (precision in highly controlled conditions, where all possible variables are held constant), intermediate precision (where some variables are controlled and some are allowed to vary), and reproducibility (precision in uncontrolled conditions, where all variables are allowed to vary). Included in the international definition of precision is a requirement that the conditions must be stipulated.

In laboratory medicine, these precision terms are roughly equivalent to "within-run," "within lab", and "lab to lab," precision, respectively.

The concept of precision defined in VIM:1993 has been superseded by newer definitions in ISO 3534 and ISO 5725. Although the VIM definition of reproducibility is incorrect, it is still cited in some CEN standards.

Sensitivity: In international standards, sensitivity is used to describe the ability of an IVD assay to determine small changes in concentration throughout the range. In laboratory medicine, sensitivity is generally used to mean the least amount of analyte in a sample that can be detected (i.e. limit of detection).

4.18 Metrological traceability

The EU requires information on the metrological traceability of calibrator and trueness control values. The Australian proposal contains a similar requirement. Traceability of patients' results is not required.

Draft FDA guidance on calibration and quality control labelling states that FDA currently requires information on calibration procedures performed and whenever possible encourages traceability of device performance to a reference method or material (i.e. a statement indicating the basis for the calibration).

Canada and Japan do not require traceability information.

4.19 Diagnostic performance characteristics

GHTF guidance states the labelling may include diagnostic performance characteristics, such as sensitivity and specificity related to the percentage of true negative and true positive values.

Canada and the EU require information on diagnostic performance characteristics.

Draft guidance from the U.S. FDA requests information when a device is compared to a “true” diagnostic state.

Australia and Japan have no requirements for diagnostic performance characteristics.

4.20 Predicate device (an existing legally marketed medical device)

The U.S. and Japan require data showing comparison to an existing, legally marketed device.

Other regulations do not have such a requirement, apart from the EU requirement to describe traceability to a higher order reference measurement procedure/material, if one is available.

4.21 Reference intervals

While GHTF guidance only states that device labelling may contain reference intervals, all five regulatory schemes and the EN standards require reference intervals along with descriptions of the reference populations.

In the EN standards, the requirement for reference intervals is qualified by “if known.”

Canada and the US also require detailed information about how the ranges were established.

The EU is explicit that the values must be in SI units. The other countries are silent on units.

4.22 User quality control

Australia, Canada, the EU and the US require that manufacturers provide users with quality control information in the instructions for use. Australia and the EU call this “internal” quality control.

Australia and the EU also require “specific validation procedures.”

The U.S. requires details of the kinds of quality control procedures and materials required by users, including information on satisfactory limits of performance, as well as descriptions of any controls that are integral components of the device (also called “internal” quality controls).

In Japan, establishing quality control procedures is solely the responsibility of the Laboratory.

The GHTF has not taken a position on providing quality control information.

4.23 Change notification

Although not addressed explicitly in labelling regulations, a requirement to update labelling when performance characteristics or instructions for use change is included in the European labelling standards.

Manufacturers are generally required by manufacturing regulations and international quality system standards (e.g. ISO 13485) to inform users of significant changes in device performance and/or instructions for use.

4.24 Limitations

Each regulatory scheme requires disclosure of certain limitations; the requirements differ in limitations of what, and the details that must be disclosed.

GHTF guidance simply states the labelling should bear “any limitations.”

Australia and the EU require a description of the “limitations of the method.”

Canada specifies “test limitations”. The draft guidance from Health Canada says the Limitations section should include requirements for personnel qualification and limitations affecting test result interpretation.

Japan requires disclosure of limitations related to the specimen.

The U.S. specifies “limitations of the procedure.” The US considers requirements for further testing with more sensitive/specific methods as limitations.

4.25 Instrument requirements

In general, the requirements in EN 591 and Japanese regulations are more specific regarding instrumentation than those of the other countries.

Some significant differences are

- Only Japan, the EU and the U.S. require environmental specifications and installation instructions.
- Only Australia, the EU and GHTF guidance require verification of proper installation.
- Only Australia, Canada and the EU require labelling to state whether any particular training is required.
- Japan, the EU, the U.S. and GHTF require checking the function of the IVD instrument.
- All but Canada require mention of the nature and frequency of the maintenance needed to ensure that the IVD operates properly and safely; and any necessary sterilization, decontamination or disinfection.
- All but Australia and Canada require cleaning instructions, if applicable.
- Only Japan and the CEN standards mention the frequency of replacing consumables and parts.
- Only U.S. and CEN request servicing information.

Only Australia, the EU and the GHTF guidance mention requirements regarding electromagnetic emission and immunity.

Annex A
(informative)

Labelling requirements of countries surveyed

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#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
1	Primary documents	EN 375:2001, Information supplied by the manufacturer with <i>in vitro</i> diagnostic reagents for professional use [10] ^b EN 591:2001, Instructions for use for <i>in vitro</i> diagnostic instruments for professional use [11]	Proposal for a New Regulatory Framework for <i>In vitro</i> Diagnostic Devices, National Coordinating Committee for Therapeutic Goods <i>In vitro</i> Diagnostic Device Working Group, March 2003 [1]	Canadian Medical Devices Regulations, Food and Drugs Act, May 1998 [5] Health Canada - Health Products and Food Branch, Guidance for the Labelling of <i>In vitro</i> Diagnostic Devices – DRAFT, January 22, 2003 [4]	Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on <i>in vitro</i> diagnostic medical devices [8]	Pharmaceutical Affairs Law (JAPAN 2003) and related documents [24]	U.S. Federal Food, drug, and Cosmetic Act [36, 37] U.S. Code of Federal Regulations, Title 21 [27-33] FDA Guidance Documents for Industry and FDA Staff [39-43]	Labelling for Medical Devices (including <i>In vitro</i> Diagnostic Devices), March 1, 2002 (Proposed) [16]
2	Scope							
3	Scope	These standards specify the requirements for a) the information supplied by the manufacturer of <i>in vitro</i> diagnostic reagents including reagent products, calibrators, control materials and kits for professional use, which hereafter are called IVD reagents. [10, §1] b) the contents of instructions for use for <i>in vitro</i> diagnostic instruments including apparatus, equipment, calibrators and control materials for professional use, hereafter called IVD instruments. This standard is not applicable to field	A national and uniform system of control over therapeutic goods supplied to the Australian market, or exported, – including IVDs – to ensure the quality, safety, efficacy and timely availability of products used in the diagnosis, curing, prevention or alleviation of disease, ailment, defect or injury.	Regulations apply to a) the sale and advertisement for sale of a medical device, and b) the importation of a medical device ... These Regulations also apply to an <i>in vitro</i> diagnostic product that is a drug or that contains a drug, as if the product were an <i>in vitro</i> diagnostic device.	This Directive shall apply to <i>in vitro</i> diagnostic medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as <i>in vitro</i> diagnostic medical devices in their own right. Both <i>in vitro</i> diagnostic medical devices and accessories shall hereinafter be termed devices. [7, Article 1, 1]	IVD reagents and IVD instruments shall be included. Buffers, traditional staining solution, diluent, calibrators or control materials that are not a part of a kit are not applied.	Labelling for <i>in vitro</i> diagnostic products [31, Sec. 809.10]	Reagents, calibrators, sample-collection devices, control materials, and related instruments or apparatus. Accessories intended specifically by manufacturers to be used together with a “parent” medical device to enable that medical device to achieve its intended purpose, should be subject to the same GHTF guidance as applies to the medical device itself. [13]

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
		repair instructions [11, §1] These standards can also be applied to accessories.						
4	Normative references							
5	Normative references	ISO 1000, <i>SI units and recommendations for the use of their multiples and of certain other units</i> [10, §2; 11, §2]	NA		Other Directives cited as noted below, e.g. for hazard warning and disposal requirements.		Other acts and regulations cited as noted below, e.g. for communication of hazard warnings.	
6	Terms and definitions							
7	Accessory	NA	A product required in the performance of a particular test or required for use with a particular IVD, e.g. a software program that is used to run an analyser.		An article which, whilst not being an <i>in vitro</i> diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose. Invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC shall not be considered to be accessories to <i>in vitro</i> diagnostic medical devices; [8, Article 1, 2(c)]		Accessories intended specifically by manufacturers to be used together with a "parent" medical device to enable that medical device to achieve its intended purpose, should be subject to the same GHTF guidance as applies to the medical device itself. [13, §5.0 NOTE 3]	
8	Accuracy	The closeness of agreement between a test result and the accepted reference value. NOTE The term accuracy, when applied to a set of test			Used throughout Directive 98/79/EC, as "trueness"		U.S. clinical laboratories use "accuracy" to mean "trueness" [35]	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
		results, involves a combination of random components and a common systematic error or bias component. [19, §3.11]						
9	Active ingredient	Constituent that participates in the reaction used to measure or detect the analyte [10, §3.1]						
10	Analyte specific reagents	NA					Antibodies, both monoclonal and polyclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. [44, § 864.4020(a)] NOTE In simple terms, an analyte specific reagent is the active ingredient of an in-house test. [40]	
11	Authorized representative	NA			Any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with			

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
					regard to the latter's obligations under this Directive: [8, Article 1, 2(g)]			
12	Bar code	NA		A unique bar code in the symbology of the Universal Product Code (UPC), the Health Industry Business Communications Council (HIBCC) or the European Article Number (EAN), assigned to a medical device by the manufacturer				
13	Batch (lot)	Defined amount of material, either starting material, intermediate or finished product which is uniform in its properties and has been produced in one process or series of processes. [10, §3.2]	A quantity of product that is a) uniform in composition, method of manufacture and probability of chemical or microbial contamination; and b) made in one cycle of manufacture and, in the case of a product that is sterilized or freeze-dried, sterilized or freeze-dried in one cycle.				One or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits. [33, Sec. 820.3 (m)]	
14	Batch code (lot number)	Code that is a distinctive combination of numbers and/or letters which specifically identifies a batch and permits its manufacturing history to be traced [10, §3.3]		Control number: a unique series of letter, numbers or symbols, or any combination of these, that is assigned to a medical device by the manufacturer and from which a history of the manufacturer, packaging, labelling and distribution of a unit, lot or batch of the device can be determined.			Control number: any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labelling, and distribution of a unit, lot, or batch of finished devices can be determined. [33, Sec. 820.3 (d)]	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
15	Calibrator	Substance, material or article intended by its manufacturer to be used to establish the measurement relationships of an <i>in vitro</i> diagnostic medical device [10, §3.4]			Any substance, material or article intended by their manufacturer either to establish measurement relationships ... in conjunction with the intended use of that device. [8, Article 1, 3]			
16	Component	NA					Any raw material, substance, piece, part, software, firmware, labelling, or assembly which is intended to be included as part of the finished, packaged, and labelled device. [33, Sec. 820.3(c)]	
17	Control material	Substance, material or article intended by its manufacturer to be used to verify the performance characteristics of an <i>in vitro</i> diagnostic medical device [10, §3.5]			Any substance, material or article intended by their manufacturer ... to verify the performance characteristics of a device in conjunction with the intended use of that device. [8, Article 1, 3]			
18	Custom-made device	NA		A medical device, other than a mass-produced medical device, that a) is manufactured in accordance with a health care professional's written direction giving its design characteristics; b) differs from medical devices generally available for sale or from a dispenser; and c) is i) for the sole use			A device that necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist; is not generally available to, or generally used by, other physicians or dentists; is not generally available in finished form for purchase or	Device for use by a single individual that has been manufactured according to a written prescription or pattern (i.e. it is custom-made); [16, §5.2]

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
				of a particular patient of that professional, or ii) for use by that professional to meet special needs arising in the course of his or her practice.			for dispensing upon prescription; is not offered for commercial distribution through labelling or advertising; and is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice. [32, §3]	
19	Dangerous substances				Chemical elements and their compounds in the natural state or obtained by any production process, which are explosive, oxidizing, flammable, toxic, harmful, corrosive, irritant, sensitizing, carcinogenic, mutagenic, or are toxic for reproduction; or dangerous for the environment, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition; [6, Article 2.1/2.2]			

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
20	Dangerous preparations				Mixtures or solutions, composed of two or more substances, which are explosive, oxidizing, flammable, toxic, harmful, corrosive, irritant, sensitizing, carcinogenic, mutagenic, or are toxic for reproduction; or dangerous for the environment. [6, Article 2.1/2.2]			
21	Dating period	NA					The period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results. [27, Sec. 600.3 (f)]	
22	Device for performance evaluation	NA			Any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises; [8, Article 1, 2(e)]		Investigational device means a device, including a transitional device, that is the object of an investigation. [32, Sec. 812.3 (g)]	
23	Expiry date	Date up to which product performance is assured by the manufacturer based on the stability of the IVD reagent [10, §3.6]			The labelling should indicate the date until which the device or one of its components can be used with complete safety; [8, Article 20]		The calendar month and year, and where applicable, the day and hour, that the dating period ends. [27, Sec. 600.3 (m)]	
24	Follow-up therapeutic procedure		A secondary medical procedure carried out following a positive result from an IVD, with the purpose of confirming a diagnosis and/or deciding on an appropriate course of treatment.					

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
25	General purpose reagent						Chemical reagent that has general laboratory application, that is used to collect, prepare, and examine specimens from the human body for diagnostic purposes, and that is not labelled or otherwise intended for a specific diagnostic application ... when combined with or used in conjunction with an appropriate analyte specific reagent (ASR) and other general purpose reagents, is part of a diagnostic test procedure or system constituting a finished <i>in vitro</i> diagnostic (IVD) test. [44, § 864.4010(a)]	
26	Graphical symbol	Visually perceptible figure with a particular meaning used to transmit information independently of language [17]					"Symbols" ... refers to the use of graphical symbols without equivalent accompanying text. [39]	
27	Health care professional	NA		A person who is entitled under the laws of a province to provide health services in the province				
28	Home use IVD	NA	An IVD supplied to lay persons, for use or interpretation in diagnosing, monitoring or identifying risk factors for a condition or state; or for collecting a sample for analysis in a testing facility.		Device for self-testing: any device intended by the manufacturer to be able to be used by lay persons in a home environment; [8, Article 1, 2(d)]			Device for self-administration: Any device intended by the manufacturer to be able to be used by lay persons in a non-clinical environment. [12]

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
29	Identifier	NA		A unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes from similar devices				
30	Immediate container (primary container)	Packaging which protects the contents from contamination and/or other effects of the external environment NOTE Examples are a sealed vial, ampoule or bottle, a foiled pouch, or a sealed plastics bag containing e.g. culture media, microtitration plates or coated tubes. [10, §3.7]						
31	<i>In vitro</i> diagnostic instrument (IVD instrument)	<i>In vitro</i> diagnostic medical device which is an instrument, apparatus or equipment NOTE In some cases a particular IVD instrument, as defined for use in human medicine, may serve also in veterinary medicine. [11, §3.5]						

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
32	<i>In vitro</i> diagnostic medical device	NA	Any therapeutic device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination (with other diagnostic goods for <i>in vitro</i> use), intended by the manufacturer to be used <i>in vitro</i> for the examination of specimens (including blood and tissue donations) derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state or a congenital abnormality or to determine safety and compatibility with a potential recipient.	<i>In vitro</i> diagnostic device (IVDD) A medical device that is intended to be used <i>in vitro</i> for the examination of specimens taken from the body.	Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used <i>in vitro</i> for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state, or concerning a congenital abnormality, or to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures. Includes specimen receptacles. Excludes products for general laboratory use unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for <i>in vitro</i> diagnostic examination; [8, Article 1, 2(b)]		<i>In vitro</i> diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in Sec. 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to Sec. 351 of the Public Health Service Act. [31, Sec. 8093 (a)]	A device for <i>in vitro</i> examination includes, for example, reagents, calibrators, sample collection devices, control materials, and related instruments or apparatus. The information provided by such an <i>in vitro</i> diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, some <i>in vitro</i> diagnostic devices, including reagents and the like, may be covered by separate regulations. [13, §5.0 NOTE 1]

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
33	<i>In vitro</i> diagnostic reagent (IVD reagent)	<i>In vitro</i> diagnostic medical device which is a reagent, reagent product, calibrator, control material or kit NOTE In some cases a particular IVD reagent, as defined for use in human medicine, may serve also in veterinary medicine. [10, §3.9]				IVD reagents exclude buffers, traditional staining solution, diluent, calibrators and control materials if not a part of kit. [25]		
34	Indication		The intended use of an <i>in vitro</i> diagnostic device (IVD).					
35	Information supplied by the manufacturer	NA			This information comprises the data on the label and in the instructions for use			
36	In-house test		A test that is developed <i>de novo</i> , or modified from a published source, or modified or adapted from any other source, within the confines or scope of a laboratory; and validated for use within that laboratory only, and is not supplied for use outside that laboratory					
37	Inner packaging		Generally defined as the labelling found immediately on the IVD or if applicable, on each individual component of a kit.					

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
38	Insert document	NA				For reagents, a document provided with the reagent(s) containing specific information in a defined format. For instruments, a document provided with an IVD instrument or corresponding parts or consumables, comprising 8 pages of A4 size bearing indispensable but brief information for proper and safe use. [25] This document will hereafter be abbreviated as DOC.I.	A document provided with the reagent(s) containing specific information in a defined format.	
39	Instructions for use (instrument)	Information supplied by the manufacturer with an IVD instrument concerning the proper use and the safe and correct operation, maintenance and basic trouble-shooting of the IVD instrument [11, §3.3]	For an IVD, can generally be defined as the documentation that accompanies an IVD ...	Directions for use: full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contra-indications and possible adverse effects.		Supplemental information to DOC.I supplied by the manufacturer with an IVD instrument. This document will hereafter be abbreviated as DOCM. The manufacturer shall provide DOCM and/or maintenance manual if an insert document is not sufficient to provide the necessary information. [25]		Information provided by the manufacturer to inform the device user of the products proper use and of any precautions to be taken. [16]

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
40	Instructions for use (reagents)	Information supplied by the manufacturer with an IVD reagent concerning the safe and proper use of the IVD reagent [45, §3.9]	For an IVD, can generally be defined as the documentation that accompanies an IVD ...	Directions for use: full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contra-indications and possible adverse effects.		Supplemental information to an insert document supplied by the manufacturer with an IVD reagent. [25]		Information provided by the manufacturer to inform the device user of the products proper use and of any precautions to be taken. [16]
41	Instrument		A machine or piece of equipment that automates a particular assay process, either by bringing samples and reagents together and measuring the result, or by measuring other qualities or parameters in the samples being tested.					
42	Intended use/intended purpose	NA		Intended purpose: The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use/or in promotional material [3]	The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use and/or in promotional materials; [8, Article 1, 2(h)]		The objective intent of the persons legally responsible for the labelling of devices. The intent is determined by such persons, expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labelling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labelled nor advertised. [29, Sect. 801.4]	The objective intent of the manufacturer or other legal entity, or person, under whose name the device is placed on the market, in respect of the application and performance of the device, as indicated in the labelling and/or promotional material. [16] The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer. [12]

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
43	Quality control	Operational techniques and activities at the point of use that are used to fulfil requirements for quality of services NOTE Internal quality control comprises all steps of activity for production of results from collection of sample and measurement of a measurable quantity to reporting of result of measurement. [10, §3.8]						
44	Kit	Set of components (reagents and/or other materials) packaged together [10, §3.10]	An <i>in vitro</i> diagnostic device that consists of a collection of reagents and/or components, or any combination of these, intended for use in the conduct of a specific test.	Test kit: an <i>in vitro</i> diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test.				
45	Kit component	<i>In vitro</i> diagnostic medical device intended to be part of a kit NOTE Typical kit components are e.g. antibody solutions, buffer solutions, calibrators or control materials. [10, §3.11]						

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#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
46	Label	Printed, written or graphic information placed on a container [10, §3.12]	A display of printed information on or attached to the goods, or on or attached to a container or primary pack in which the goods are supplied, or supplied with such a container or pack.	The LABEL as defined in the Food and Drugs Act includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package.			A display of written, printed, or graphic matter upon the immediate container of any article... The term "immediate container" does not include package liners. [36, Sec. 201(k)]	Information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices. [16]
47	Labelling	NA	For IVDs, includes, but is not limited to, individual IVD labels, outer packaging and the instructions for use. Instructions for use are commonly provided in the form of a package insert.	Labelling for IVDs includes, but is not limited to, the immediate device container label, the reagent/component label and package insert. [4, §3.1]			All labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. The term "accompanying" is interpreted liberally [see NOTE 2 for examples of intent]. [36, Sec. 201(m)]	An inclusive term to describe the label, instructions for use, maintenance instructions, packaging insert and other information associated with the device. [16]
48	Manufacturer	The manufacturer is the entity which has taken legal responsibility for the IVD reagent./instrument [10, §3.1.2 NOTE] [11, §5.3 NOTE]	The person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the persons name, whether or not it is the person, or another person acting on the persons behalf, who carries out those operations. OR the person who, with a view to supplying the device under the persons name, does one or more of the following using ready-made products a) assembles the device;	A person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.	The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-	The natural or legal person who has approved for manufacturing approved IVD. The approval requires qualification of facilities, production and/or quality management, and of such person.	Any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabelling, remanufacturing, repackaging, or specification development, and initial distributors of foreign entities	

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			b) packages the device; c) processes the device; d) fully refurbishes the device; e) labels the device.		made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient; [8, Article 1, 2(f)]		performing these functions. [33, Sec. 820.3 (o)]	
49	Material safety data sheet (MSDS)	NA		A document on which words, figures or symbols disclosing the information referred to in subparagraphs 13(a)(i) to (v) [regarding a hazardous chemical] may be written, printed or otherwise expressed; [46, §11.(1)]			written or printed material concerning a hazardous chemical which is prepared in accordance with 29 CFR 1910.1200 (g) [34, Sec. 1910.1200 (c)]	
50	Medical device	NA	Therapeutic device Therapeutic goods consist of instruments, apparatus, appliances, materials or other articles (whether for use alone or in combination), together with any accessories or software required for their proper functioning, which do not achieve their principal intended action by pharmacological, chemical, immunological or metabolic means. However, they may be assisted in their function by pharmacological, chemical, immunological	Any article, instrument, apparatus or contrivance, including any component, part or accessory thereof. A device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.	Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of — diagnosis, prevention, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation		An instrument, apparatus, implement, machine, contrivance, implant, <i>in vitro</i> reagent, or other similar or related article, including any component, part, or accessory, which is 1) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, or	Harmonized definition of the term "medical device" [13] "Medical device" means any instrument, apparatus, implement, machine, appliance, implant, <i>in vitro</i> reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for one human beings for one or more of the specific

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
			or metabolic means. This definition applies to goods or components of goods that are represented in any way to be for therapeutic use, or that are likely to be taken to be for therapeutic use, because of the way in which they are presented or for any other reason. Therapeutic use means use in, or in connection with — preventing, diagnosing, curing or alleviating a disease, ailment defect or injury in persons or animals; or — influencing, inhibiting or modifying a physiological process in persons or animals; or — testing the susceptibility of persons or animals to a disease or ailment; or — influencing, controlling or preventing conception in persons; or — testing for pregnancy in persons; or — the replacement or modification of parts of the anatomy in persons or animals. [2]		or compensation for an injury or handicap, — investigation, replacement or modification of the anatomy or of a physiological process, — control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; [8, Article 1, 2(a)]		2) intended to affect the structure or any function of the body of man. [36, Sec. 201(h)]	purpose(s) of — diagnosis, prevention, monitoring, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of or compensation for an injury, — investigation, replacement, modification, or support of the anatomy or of a physiological process, — supporting or sustaining life, — control of conception, — disinfection of medical devices, — providing information for medical purposes by means of <i>in vitro</i> examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means. [13, §5.0]

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
51	Medical device family	NA		A group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use. [5, Part 1, Sec. 1.]				
52	Medical device group	NA		A medical device comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name. [5, Part 1, Sec. 1.]				
53	Medical device family	NA		A collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that differ only in the number and combination of products that comprise each group. [5, Part 1, Sec. 1.]				
54	Name (device/product)	NA		In respect of a medical device, includes any information necessary for the user to identify the device and to distinguish it from similar devices.		Device or product name which is stated on the approval form.	Proper name, as applied to a product: the name designated in the license for use upon each package of the product. [27, Sec. 600.3 (k)]	
55	Near patient <i>in vitro</i> diagnostic device	NA		An IVDD that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or at the bedside				

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56	Outer container (sales packaging)	Material used in the packaging of the immediate container(s) of (an) IVD reagent(s) consisting of a single entity or an assembly of different or identical components [10, §3.13]	Can generally be defined as the box, carton, etc., in which the IVD is presented. IVDs are usually removed from their outer packaging prior to use.					
57	Performance evaluation (of an <i>in vitro</i> diagnostic device)	An investigation of the performance of an <i>in vitro</i> diagnostic medical device based upon data already available, scientific literature and/or performance evaluation studies. [48]					Investigation is a clinical investigation or research involving one or more subjects to determine the safety and/or effectiveness of a device. [32, Sec. 812.3 (h)]	A premarket study of a medical device intended for the <i>in vitro</i> examination of specimens derived from the human body, undertaken in specialist laboratories for medical analysis or in other appropriate environments, outside the manufacturer's own premises, in order to demonstrate the device conforms to all relevant Essential Principles for Safety and Performance [16]
58	Precautions	NA		[Statements that] alert the user to the special care or procedures necessary for the safe and effective use of the IVDD.			Statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. [ANSI Z535.4-1998] It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
							care necessary to avoid damage to a device that may occur as a result of use or misuse. NOTE The distinction between warnings and precautions is a matter of degree of likelihood and seriousness of the hazard. [49]	
59	Predicate device	NA	A device that has been previously evaluated and is currently listed or registered on the ARTG. [2]				A legally marketed device(s) to which equivalence is drawn, [which must be] a device that was legally marketed prior to May 28, 1976 (preamendments device), or a device which has been reclassified from Class III to Class II or I. [50, Sec. 807.92]	
60	Product	NA					Components, manufacturing materials, in-process devices, finished devices, and returned devices. [33, Sec. 820.3 (r)]	
61	Professional use	Use by personnel who have received special education and training with regard to procedures utilizing <i>in vitro</i> diagnostic medical devices [10, §3.14]						

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003 ^a	United States	GHTF
62	Reagent		A solution of highly specific biological or chemical substances that is able to react with target substances in samples being tested, and to give a product that can be measured (as in a quantitative assay) or seen (as in a qualitative assay).					
63	Reagent product (reagent carrier)	Product in which the reagents are fixed to or included in a carrier Examples: reagent strips, slides, discs and sticks. [10, §3.15]						
64	Shelf life	Period until expiry date [10, §3.16]						
65	Specimen	Biological material which is obtained in order to detect or to measure one or more quantities [10, §3.17]						The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantity or characteristic to determine the character of the whole. [12]
66	Specimen receptacles	NA			those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of <i>in vitro</i> diagnostic examination [8, Article 1, 2(b)]			

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67	Sponsor		a) a person who exports, or arranges the exportation of, the goods from Australia; OR b) a person who imports, or arranges for the importation of, the goods into Australia; OR c) a person, who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); but does not include a person who 1) exports, imports or manufactures the goods; OR 2) arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in Australia.					
68	Stability	Ability of an IVD reagent when kept under specified conditions, to retain throughout the shelf						

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		life its properties and/or performance within limits specified by the manufacturer [10, §3.18]						
69	System	NA	A term often used to refer to the reagents, instruments and accessories required to perform a given test.	A medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name.				
70	Therapeutic use		Use in or in connection with a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or b) influencing, inhibiting or modifying a physiological process in persons or animals; or c) testing the susceptibility of persons or animals to a disease or ailment; or d) influencing, controlling or preventing conception in persons, or e) testing for pregnancy in persons, or f) the replacement or modification of parts of the anatomy in persons or animals.					

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71	Trueness	Closeness of agreement between the average value obtained from a large series of test results and an accepted reference value [ISO 3534-1] [10, §3.19]			Directive 98/79/EC uses "accuracy" synonymously with "trueness", whereas the term "accuracy" includes both "trueness" and "precision," according to ISO 3534-1 and ISO 5725-1. [10, §3.19 NOTE]		US clinical laboratories use "accuracy" to mean "trueness" [35]	
72	Warnings	NA		[Statements that] alert the user to potential serious adverse reactions and safety hazards that can occur in the proper use, or misuse, of an IVD.			A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury. [ANSI Z535.4-1998] It may also describe potential serious adverse reactions and safety hazards. The designation of a hazard alert as a "warning" is reserved for the most significant problems. NOTE The distinction between warnings and precautions is a matter of degree of likelihood and seriousness of the hazard. [49]	
73	Labelling principles and general requirements							
74	Purpose of labelling		[Provide] information needed to use the IVD safely, taking account of the training and knowledge of potential users, and [1, Appendix B.8.1 c)]		[Provide] the information needed to use it safely and properly, taking account of the training and knowledge of the potential users. [8, Annex I.B.8.1]	To provide necessary information to laboratory personnel for the proper use of IVD devices and to ensure the safety of patients. [25]		Labelling serves to communicate safety- and performance-related information to users of medical devices and/or patients as well as to identify individual devices. Such information may appear on the device