

## **Preface**

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

There are no restrictions on the reproduction, distribution, translation or use of this document. However, incorporation of this document, in part or in whole, into any other document does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

## 1.0 Introduction

The primary way in which the GHTF achieves its goals is through the production of a series of guidance documents that together describe a global regulatory model for medical devices. The purpose of such guidance is to harmonize the documentation and procedures that are used to assess whether a medical device conforms to the regulations that apply in each jurisdiction. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This document has been developed to encourage and support global convergence of regulatory systems. It is intended for use by Regulatory Authorities (RAs), Conformity Assessment Bodies (CABs) and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. It seeks to strike a balance between the responsibilities of Regulatory Authorities to safeguard the health of their citizens and their obligations to avoid placing unnecessary burdens upon the industry.

Labelling<sup>1</sup> serves to identify a device and its manufacturer, and to communicate information on safety, use and performance. It is intended for users of medical devices, including IVD medical devices, both professional and lay, as appropriate, and for relevant third parties. RAs require and specify information that manufacturers are expected to incorporate in the labelling when the device is placed onto the market. The GHTF identified as a priority the need to harmonize the content of the labelling and has published guidance on the subject as GHTF/SG1/N043:2005 *Labelling for Medical Devices*.

This document **supersedes** that previous version. It has been changed to:

- indicate which information should be included on the label and in the instructions for use, and
- provide a separate section within the document for IVD medical devices.

Where other guidance documents within the series are referenced within this text, their titles are italicised for clarity.

Study Group 1 of the Global Harmonization Task Force (GHTF) has prepared this guidance document. Comments or questions should be directed to either the Chairman or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF web page<sup>2</sup>.

## 2.0 Rationale, Purpose and Scope

### 2.1 Rationale

Consistent worldwide requirements for medical device labelling would offer significant benefits to the manufacturer, user, patients and RAs. Eliminating or reducing differences

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<sup>1</sup> Some regional and national regulations use the term ‘information supplied by the manufacturer’ rather than ‘labelling’. This document uses the term ‘labelling’.

<sup>2</sup> [www.ghtf.org](http://www.ghtf.org)

between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

## 2.2 Purpose

To provide guidance to manufacturers and RAs on the content of the label and the instructions for use that provide users, both professional and lay as appropriate, and/or patients, and any relevant third parties with information such as:

- the device's identity;
- the identity of the manufacturer;
- the device's intended use/purpose;
- how the device should be used, maintained and stored;
- any residual device risks, warnings, limitations or contraindications;
- the device's performance.

whilst also promoting:

- labelling commensurate with the technical knowledge, experience, education or training of intended users;
- consistent use of terminology;
- use of symbols;
- the avoidance of prescriptive country-specific requirements for text, content, or format of labelling that offers no benefit to the device user or, where applicable, the patient.

## 2.3 Scope

This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Information Document Concerning the Definition of the Term "Medical Device"*.

Advertising and promotional materials are outside the scope of this document.

## 3.0 References

### **GHTF final documents<sup>3</sup>**

GHTF/SG1/N044:2008 *Role of Standards in the Assessment of Medical Devices*.

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<sup>3</sup> The listed documents are subject to periodic review and may be superseded by later documents. The reader is encouraged to refer to the GHTF website [www.ghtf.org](http://www.ghtf.org) to confirm whether the referenced documents remain current. Revisions of both GHTF/SG1/N029:2005 and GHTF/SG1/N041:2005 are at an advanced stage.

GHTF/SG1/N029:2005 *Information Document Concerning the Definition of the Term “Medical Device”*.

GHTF/SG1/N041:2005 *Essential Principles of Safety and Performance of Medical Devices*.

GHTF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer*.

## 4.0 Definitions

**Clinical investigation:** any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device.

**Information supplied by the manufacturer:** means ‘Labelling’.

**Label:** written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

**Labelling:** the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

**Lay person:** individual that does not have formal training in a relevant field or discipline.

**Instructions for use:** information provided by the manufacturer to inform the device user of the medical device’s intended purpose and proper use and of any precautions to be taken.

**Intended use / purpose:** 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.

**Performance evaluation for an IVD medical device:** investigation process of an IVD medical device for the purpose of establishing or verifying its performance.

**Single use device:** means the medical device is intended to be used on an individual patient during a single procedure and then disposed of. It is not intended to be reprocessed and used again.

**User:** the person, either professional or lay, who uses a medical device. The patient may be the user.

## 5.0 General Principles

This section describes the general principles that apply equally to all medical devices, including IVD medical devices.

The primary purpose of labelling is to identify the medical device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on packaging or as instructions for use. The following principles are recommended.

- The medium, format, content, legibility, and location of the label and instructions for use should be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may include separate information for the professional user and the lay person.
- The information required on the label, should be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.
- Where the manufacturer supplies multiple devices to a single user and/or location, it may be sufficient to provide only a single copy of the instructions for use. In these circumstances, the manufacturer should provide further copies upon request.
- Instructions for use may not be needed or may be abbreviated for devices if they can be used safely and as intended by the manufacturer without any such instructions for use.
- Labels should be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes<sup>4</sup>.
- Instructions for use may be provided to the user either in paper or non-paper format (e.g. electronic). They may be supplied by various means either with the medical device or separate from it. Examples of other means are information displayed on a screen incorporated into the device, information downloaded from the manufacturer's web site using the internet, and machine-readable sources. The means chosen should be appropriate for, and accessible to, the anticipated user population.
- Where instructions for use are provided on a medium other than paper, the manufacturer should ensure the user has information on how to:
  - a) view the instructions for use;
  - b) access the correct version of the instructions for use; and
  - c) obtain a paper version of the instructions for use.

**Note:** the RA may set the conditions under which such non-paper format should be provided to guarantee a high level of protection of health. Those conditions may specify the types of devices that can use a non-paper format and the requirements the manufacturer needs to respect, such as, that the manufacturer should upon request provide a paper version of the instructions for use free of charge.

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<sup>4</sup> Also refer to the final version of the draft guidance document GHTF/AH/(PD2)N2R2 *Unique Device Identification (UDI) System for Medical Devices* for information on labels for UDI purposes.

- Residual risks which are required to be communicated to the user<sup>5</sup> and/or other person should be included as limitations, contraindications<sup>6</sup>, precautions or warnings in the labelling.
- The use of internationally recognised symbols<sup>7</sup> should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the user. Where the meaning of the symbol is not obvious to the device user, e.g. for a newly introduced symbol, an explanation should be provided within the instructions for use.
- Country-specific requirements for the content of the labelling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.
- Where national legislation, such as customs statutes, trade agreements and the like, include requirements for additional documentation to accompany the medical device, there may be an inconsistency between the additional documentation and the content of medical device labelling described in this guidance document. An example is a customs requirement to indicate the ‘country of origin’ of the medical device which does not necessarily align with the address of the manufacturer indicated in the labelling according to Section 6.1(c) or Section 7.1(c) of this document.
- Provided that safe and correct use of the device is ensured, a RA may authorise labelling to be in one or more language(s) other than its national language(s).

## **6.0 Label and Instructions for Use for Medical Devices other than IVD Medical Devices**

### **6.1 Content of the Label**

The label should contain the following particulars which may appear on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

- a) The name or trade name of the medical device.
- b) The details strictly necessary for a user to identify the device and its use, e.g. ‘cardiac ablation catheter 10 French / 20 cms’ or ‘paediatric thermometer’ or ‘tongue depressor’, and a product catalogue code.

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<sup>5</sup> See essential principle 5.2 of GHTE/SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices*.

<sup>6</sup> ‘Contraindications’ is a term that is not relevant to IVD medical devices.

<sup>7</sup> Such as those found in ISO 15223-1:2007 *Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements*.

- c) The name and address of the manufacturer<sup>8</sup> in a format that is recognisable and allows the location of the manufacturer to be established<sup>9</sup>.
- d) For imported devices, the name and postal address of the authorised representative, or importer or distributor established within the importing country/jurisdiction may be required. This information may be added by the authorised representative, importer, or distributor within the country of import, rather than be provided by the manufacturer, in which case, the additional label should not obscure any of the manufacturer's labels.
- e) Where appropriate, an indication that the device contains or incorporates a medicinal or biological substance, e.g. heparin coated catheter.
- f) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate, to allow post-market action to be taken if there is a need to trace or recall the device.
- g) An unambiguous indication of the date until when the device may be used safely, expressed at least as the year and month (e.g. on devices supplied sterile or single use disposable devices), where this is relevant.
- h) Where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable.
- i) An indication of any special storage and/or handling condition that applies.
- j) If the device is supplied sterile, an indication of its sterile state and, where appropriate, the sterilization method.
- k) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the medical device as relevant, and to any other person where appropriate (e.g. 'CAUTION – HOT SURFACE' or 'THIS PRODUCT CONTAINS LATEX'). This information may be kept to a minimum in which case more detailed information should appear in the instructions for use.
- l) If the device is intended for single use, an indication of that fact.

**Note:** According to Note 5 of GHF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer*, any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device. As a consequence, a reprocessor of a single use device would be subject to the same requirements as those applicable to a manufacturer. In those jurisdictions where reprocessing of single use devices is allowed, the fact that a single use device has been reprocessed should be indicated on the label also”.

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<sup>8</sup> As defined in GHF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer*.

<sup>9</sup> An abbreviated version of the address may be sufficient on the label if the device is accompanied by instructions for use that provide a full address.

- m) If the device is for use by a single individual and has been manufactured according to a written prescription or pattern (i.e. it is custom made), an indication of that fact.
- n) If the device is intended for premarket clinical investigation only, an indication of that fact.

**Note:** In this situation, some of the label content listed above may not apply.

- o) If the device is intended for non-clinical research, teaching or testing purposes only, an indication of that fact.

**Note:** In this situation, some of the label content listed above may not apply.

- p) If the device is intended for presentation or demonstration purposes only, an indication of that fact.

**Note:** In this situation, some of the label content listed above may not apply.

For guidance on the information to be incorporated within the label for Unique Device Identification (UDI) purposes, refer to the GHTF guidance document on this subject<sup>10</sup>.

## 6.2 Content of the Instructions for Use

The instructions for use should contain the following particulars:

- a) The name or trade name of the medical device.
- b) The name and address of the manufacturer in a format that is recognisable and allows the location of the manufacturer to be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance.
- c) The device's intended use/purpose including the intended user (e.g. professional or lay person), as appropriate.
- d) The performance of the device intended by the manufacturer.
- e) Where the manufacturer has included clinical investigations as part of premarket conformity assessment to demonstrate conformity to Essential Principles, a summary of the investigation, outcome data and clinical safety information, or a reference as to where such information may be accessed.
- f) Any residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard.
- g) Specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it.

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<sup>10</sup> See the final version of the draft document GHTF/AH/(PD2)N2R2 *Unique Device Identification (UDI) System for Medical Devices*.



- h) If the device contains, or incorporates, a medicinal substance and/or material of biological origin, identification of that substance or material, as appropriate.
- i) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilization, final assembly, calibration, etc.).
- j) Any requirements for special facilities, or special training, or particular qualifications of the device user and/or third parties.
- k) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:
  - details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection;
  - identification of any consumable components and how to replace them;
  - information on any necessary calibration to ensure that the device operates properly and safely during its intended life span;
  - methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing medical devices.
- l) An indication of any special storage and/or handling condition that applies.
- m) If the device is supplied sterile, instructions in the event of the sterile packaging being damaged before use.
- n) If the device is supplied non-sterile with the intention that it is sterilized before use, the appropriate instructions for sterilization.
- o) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.
- p) For devices intended for use together with other medical devices and/or general purpose equipment:
  - information to identify such devices or equipment, in order to obtain a safe combination,and/or
  - information on any known restrictions to combinations of medical devices and equipment.
- q) If the device emits hazardous, or potentially hazardous levels of radiation for medical purposes:
  - detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation;

- the means of protecting the patient, user, or third party from unintended radiation during use of the device;
- r) Information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information should cover, where appropriate:
- warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;
  - warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
  - warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);
  - if the device administers medicinal or biological products, any limitations or incompatibility in the choice of substances to be delivered;
  - warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device;
  - precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction of the patient or user.
- s) Warnings or precautions to be taken related to the disposal of the device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:
- infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);
  - environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation);
  - physical hazards (e.g. from sharps).
- t) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.
- u) Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

## 7.0 Label and Instructions for use for IVD Medical Devices

### 7.1 Content of the Label

The label should contain the following particulars which may appear on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

- a) The name or trade name of the IVD medical device.
- b) Where not obvious, the details strictly necessary for a user to identify the IVD medical device and its use, e.g. 'HIV-1/HIV-2 Antibody Test' or 'Blood Glucose meter' or 'Blood Gas Analyzer'.
- c) The catalogue number of the IVD medical device.
- d) The name and address of the manufacturer<sup>11</sup> in a format that is recognisable and allows the location of the manufacturer to be established<sup>12</sup>.
- e) For imported IVD medical devices, the name and postal address of either the authorised representative, or importer or distributor established within the importing country/jurisdiction may be required. This information may be added by the authorised representative, importer or distributor within the country of import, rather than be provided by the manufacturer, in which case, the additional label should not obscure any of the manufacturer's labels.
- f) An indication that the device is for in vitro diagnostic use.
- g) The batch code/lot number or the serial number of the IVD medical device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate, to allow post-market action to be taken if there is a need to trace or recall the IVD medical device. However for accessories this may be substituted with a control number and for software it should be substituted with a version number.
- h) An unambiguous indication of the date until when the IVD medical device may be used safely, expressed at least as the year and month (e.g. on reagents or consumables), where this is relevant.
- i) For instruments, where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable.
- j) Where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package.

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<sup>11</sup> As defined in GHTF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer*.

<sup>12</sup> An abbreviated version of the address may be sufficient if the device is accompanied by instructions for use that provide a full address.

- k) An indication of any special storage and/or handling condition that applies.
- l) If the IVD medical device is supplied as sterile, an indication of its sterile state and, where appropriate, the sterilization method.
- m) Warnings or precautions to be taken that need to be brought to the immediate attention of the professional user, the lay person or other person (e.g. 'CAUTION – LASER' or 'CONTAINS POTENTIALLY INFECTIOUS MATERIAL'). This information may be kept to a minimum in which case more detailed information will appear in the instructions for use.
- n) Where relevant, if the IVD medical device is intended for single use and there is a potential risk of re-use, (e.g. blood collection tubes), an indication of that fact.
- o) If the IVD medical device is intended for premarket performance evaluation only, an indication of that fact.

**Note:** In this situation, some of the label content listed above may not apply.

- p) If the IVD medical device is intended for non-clinical research or use, teaching or testing purposes only, an indication of that fact. That indication may be added by the authorised representative, importer or distributor within the country of import, rather than be provided by the manufacturer.

**Note:** In this situation, some of the label content listed above may not apply.

- q) If the IVD medical device is intended for presentation or demonstration purposes only, an indication of that fact. That indication may be added by the authorised representative, importer or distributor within the country of import, rather than be provided by the manufacturer.

**Note:** In this situation, some of the label content listed above may not apply.

- r) IVD medical device kits include individual reagents and articles that may be made available as separate IVD medical devices. In this situation, these IVD medical devices should comply with the label content in this section.

For more guidance on the inner and outer container label elements refer to the ISO 18113 standard series.

For guidance on the information to be incorporated within the label for Unique Device Identification (UDI) purposes, refer to the GHTF guidance document on this subject<sup>13</sup>.

## 7.2 Content of the Instructions for Use

The instructions for use should contain the following particulars:

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<sup>13</sup> See the final version of the draft document GHTF/AH/(PD2)N2R2 *Unique Device Identification (UDI) System for Medical Devices*.

- a) The name or trade name of the IVD medical device.
- b) The IVD medical device's intended use/purpose (further guidance on elements which, when relevant, should be included in the intended use/purpose is provided in the STED document<sup>14</sup>):
  - what is detected;
  - its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);
  - the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
  - whether it is automated or not;
  - whether it is qualitative or quantitative;
  - the type of specimen(s) required (e.g. serum, plasma, whole blood, tissue biopsy, urine); and
  - testing population.
- c) An indication that it is for in vitro diagnostic use.
- d) The intended user, as appropriate (e.g. lay person).
- e) Test principle.
- f) A description of the reagent, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only).

**Note:** IVD medical device kits include individual reagents and articles that may be made available as separate IVD medical devices. In this situation, where appropriate, these IVD medical devices should comply with the instructions for use content in this section.
- g) A list of materials provided and a list of special materials required but not provided.
- h) For IVD medical devices intended for use together with other medical devices, including IVD medical devices, and/or general purpose equipment
  - information to identify such devices or equipment, in order to obtain a safe combination,and/or
  - information on any known restrictions to combinations of medical devices and equipment.
- i) An indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions that apply.

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<sup>14</sup> See GHF/SG1/N063:2011 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices (STED)*.

- j) In use stability which may include, the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant.
- k) If the IVD medical device is supplied as sterile, instructions in the event of the sterile packaging being damaged before use.
- l) Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the IVD medical device. This information should cover, where appropriate:
- warnings, precautions and/or measures to be taken in the event of malfunction of the IVD medical device or its degradation as suggested by changes in its appearance that may affect performance;
  - warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
  - warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);
  - precautions related to materials incorporated into the IVD medical device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction.
- m) Any warnings and/or precautions related to potentially infectious material that is included in the IVD medical device.
- n) Where relevant, requirements for special facilities (e.g. clean room environment) or special training (e.g. radiation safety), or particular qualifications of the device user.
- o) Conditions for collection, handling, and preparation of the specimen.
- p) Details of any preparatory treatment or handling of the IVD medical device before it is ready for use (e.g. reconstitution, calibration, etc.).
- q) The information needed to verify whether the IVD medical device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:
- details of the nature, and frequency, of preventative and regular maintenance (including cleaning and disinfection);
  - identification of any consumable components and how to replace them;

- information on any necessary calibration to ensure that the IVD medical device operates properly and safely during its intended life span;
  - methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing IVD medical devices, e.g. contaminated surfaces.
- r) Where relevant, recommendations for quality control procedures.
- s) The metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order.
- t) Assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing should be considered.
- u) Analytical performance characteristics, such as sensitivity, specificity, and accuracy (which is a combination of trueness and precision).
- v) Where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity.
- w) Where relevant, reference intervals.
- x) Information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen/sample) that may affect the performance of the assay.
- y) Warnings or precautions to be taken related to the disposal of the device, its accessories, and the consumables used with it, if any. This information should cover, where appropriate:
- infection or microbial hazards (e.g. consumables contaminated with potentially infectious substances of human origin);
  - environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation);
  - physical hazards (e.g. explosion).
- z) For IVD medical devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.
- aa) Where relevant, a bibliography.
- bb) The name and address of the manufacturer in a format that is recognisable and allows the location of the manufacturer to be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance.
- cc) Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.



## 最終文書

### Global Harmonization Task Force

タイトル：医療機器のラベルおよび使用説明書

作成グループ：Global Harmonization Task Force の作業グループ 1

承認：Global Harmonization Task Force

日付：2011年9月16日

GHTF 議長 浅沼一成

本文書は、欧州、アメリカ合衆国(USA)、カナダ、日本、およびオーストラリアにおける医療機器規制当局および業界団体からの代表者による自主的国際グループである Global Harmonization Task Force が作成した。

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## 序文

本文書は、医療機器規制当局および規制対象の業界からの代表者による自主的グループである Global Harmonization Task Force が作成した。本文書は、医療機器を規制するに当たり使用する拘束力のないガイダンスを提供することを目的としており、その作成において協議が行われた。

本文書の複製、配布、翻訳、および使用に制限はないが、本文書の一部または全文が他の文書に組み込まれた場合、Global Harmonization Task Force がこれにいかなる保証を与えることを意味するものではない。

## 1.0 緒言

GHTF がその目的を達成する主な方法は、医療機器に関する世界的な規制モデルを全体として説明するような一連のガイダンス文書を作成することである。このようなガイダンスの目的は、各管轄地域の適用規制に医療機器が適合しているか否かを審査する際に用いられる文書および手順を統合化することである。各管轄地域間の相違を解消することにより、規制遵守の費用が削減され、新しい技術や治療法へのアクセスがより早く患者に提供されることとなる。

本文書は、規制システムの国際的な統合を奨励、支援する目的で作成されている。これは規制当局(RA)、適合性評価機関(CAB)、および産業界での使用を意図した文書であり、公衆衛生の利益のための医療機器のコントロールにおける経済的かつ効果的アプローチを安定的に確立させる上で有用である。本文書は、市民の健康を保護するという規制当局の責任と産業界に対して不必要な負担を負わせないという義務との間のバランスを取ることを目指している。

ラベリング<sup>1</sup>は、機器とその製造者を識別し、安全性、使用法、および性能に関する情報を伝えるために用いられ、体外診断用(IVD)医療機器を含む医療機器の適切な使用者（専門家および一般の使用者）ならびに関連する第三者に向けたものである。RA は、製造者が機器を市販する際にラベルに組み込むべき情報について、これを要請し、具体的内容を定める。GHTF では、ラベリング内容の調和の必要性を優先的事項と認識し、これに関するガイダンス GHTF/SG1/N043:2005 *Labelling for Medical Devices*（医療機器のラベリング）を公表している。

本文書はこの以前の版に置き換えられるものである。変更内容は以下の通り。

- ラベルおよび使用説明書に記載すべき情報を明記した。
- 文書内に IVD 医療機器に関する個別のセクションを設けた。

本文内でガイダンスシリーズの他の文書を参照する場合は、分かりやすいようにタイトルをイタリック体にした。

本ガイダンス文書は Global Harmonization Task Force (GHTF)の作業グループ 1 が作成した。コメントや質問は、議長または GHTF 作業グループ 1 の事務局長まで連絡されたい。連絡先詳細は GHTF のウェブページ<sup>2</sup>に掲載されている。

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<sup>1</sup> 地域および国の規制の中には、「ラベリング」という用語の代わりに「製造者が提供する情報」という用語を用いているものもある。本文書では「ラベリング」という用語を用いる。

<sup>2</sup> [www.gh tf.org](http://www.gh tf.org)

## 2.0 根拠、目的、範囲

### 2.1 根拠

医療機器のラベリングに関する世界的に一貫した要件があれば、製造者、使用者、患者、および RA にとって大きな利益となるであろう。各管轄地域の間の違いを解消または減少させることにより、規制遵守の費用が削減され、患者は新しい技術や治療法により早くアクセスできることとなる。

### 2.2 目的

ラベルおよび使用説明書の内容に関して、製造者および RA にガイダンスを提供すること。このようなラベルおよび使用説明書は、該当する使用者（専門家および一般の使用者）および／または患者、ならびに関連する第三者に、以下のような情報を提供するものである。

- 機器の識別情報
- 製造者の識別情報
- 機器において意図されている使用法／目的
- 機器の使用、管理、および保管の方法
- 機器の残留リスク、警告、制限、または禁忌
- 機器の性能

また、以下を促進する。

- ラベル内容が、想定される使用者の技術的知識、経験、教育、訓練に見合ったものであること。
- 一貫した用語が使用されること。
- 記号の使用。
- ラベリングの本文、内容、書式に関して、機器の使用者または該当する場合は患者に対して何ら利益をもたらさないような、国固有の要件を避けること。

### 2.3 範囲

本文書は、GHTF の文書 *Information Document Concerning the Definition of the Term "Medical Device"* (用語「医療機器」の定義に関する情報資料) に記載されている医療機器の定義に該当するすべての製品に適用される。

広告および販促資料は、本文書の対象外である。