



FINAL DOCUMENT

Title: Labelling for Medical Devices

Authoring Group: Study Group 1

Endorsed by: The Global Harmonization Task Force

Date: June 3, 2005

[Signature], GHTF Chair

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide *non-binding* guidance to regulatory authorities 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 or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

Copyright © 2000 by the Global Harmonization Task Force

Table of Contents

1.0	Introduction.....	4
2.0	Rationale, Purpose and Scope.....	5
2.1	Rationale	5
2.2	Purpose.....	5
2.3	Scope.....	5
3.0	References.....	5
4.0	Definitions.....	5
5.0	Labelling Requirements	6
5.1	General Principles	6
5.2	Content of Labelling	7

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.

This document supersedes the document GHTF/SG1/N9:2000 *Labelling for Medical Devices* of February 24, 2000 and includes added guidance on the labelling of medical devices for the *in vitro* examination of specimens derived from the human body.

1.0 Introduction

The objective of the Global Harmonization Task Force (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade whilst preserving the right of participating members to address the protection of public health by regulatory means considered to be most suitable.

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, Conformity Assessment Bodies 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. Study Group 1 of the GHTF supports and encourages regulatory harmonization but recognises that some Regulatory Authorities may have to reflect different local needs when they introduce new regulations on labelling. However, Regulatory Authorities that are developing regulatory requirements to address device labelling, or amending existing ones, are encouraged to consider the adoption of the recommendations described in this document, as this will help to reduce the diversity of labelling requirements worldwide and facilitate the process of harmonization.

Labelling serves to communicate safety and performance related information to users of medical devices and/or patients as well as to identify individual devices. Regulatory Authorities require and specify information that manufacturers are expected to incorporate on the labelling when the device is placed onto the market. The GHTF identified as a priority the need to harmonize requirements for labelling and has published guidance on the subject entitled *Labelling for Medical Devices* (SG1/N009 of February 24, 2000) that applied to the majority of medical devices but not to *in vitro* diagnostic devices. This revision includes added guidance on the labelling of medical devices for the *in vitro* examination of specimens derived from the human body **and supersedes the previous version.**

The regulatory requirements of some countries do not, at this time, align fully with this guidance.

Study Group 1 of the Global Harmonization Task Force (GHTF) has prepared this guidance document. Comments or questions about it should be directed to either the Chairman or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF web page¹.

¹ www.ghtf.org

2.0 Rationale, Purpose and Scope

2.1 Rationale

Consistent worldwide labelling requirements would offer significant benefits to the manufacturer, user and/or patient, and to Regulatory Authorities. Eliminating or reducing differences 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 Regulatory Authorities on medical device labelling that clearly informs the user of:

- its identity and intended use/purpose;
- how it should be used, maintained and stored;
- any residual risks, warnings or contra-indications;

whilst also promoting:

- labelling commensurate with the technical knowledge, experience, education or training of intended users;
- use of symbols.
- the avoidance of prescriptive country-specific requirements for labelling text, content, or the format of labels or labelling that offer no user or patient benefit.

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"*, including those used for the *in vitro* examination of specimens derived from the human body.

Note: In some regulatory schemes promotional documentation/materials may be considered labelling. Such materials are outside the scope of this document.

3.0 References

GHTF final documents

GHTF/SG1/N12:2000 *Role of Standards in the Assessment of Medical Devices.*

GHTF/SG1/N29:2005 *Information Document Concerning the Definition of the Term "Medical Device"*

GHTF/SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices*

4.0 Definitions

Clinical investigation: Any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device. (Source – ISO/DIS 14155-1)

Label: Written, printed or graphic 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.

Labelling / information supplied by the manufacturer: Written, printed or graphic matter

- affixed to a medical device or any of its containers or wrappers, or,
- accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents.

Note: Some regional and national regulations refer to ‘Labelling’ as ‘Information supplied by the manufacturer’ (Source – ISO 13485)

Lay person : individual that does not have formal training in a specific field or discipline. (Source ISO 18113-1)

Instructions for use: Information provided by the manufacturer to inform the device user of the product’s 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 (Source – 21 CFR 801.4)

Medical device: Refer to GHTF guidance document: *Information Document Concerning the Definition of the Term “Medical Device”* (SG1/N029).

Performance evaluation: Review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

Reprocessing: Reprocessing includes all the steps performed to make a contaminated reusable device or a single-use device ready for use with a patient. The steps may include cleaning, functional testing, repackaging, relabelling, disinfection or sterilisation. (Source – FDA)

Reprocessor: Any entity that performs reprocessing activities. (Source – FDA)

5.0 Labelling Requirements

5.1 General Principles

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 itself, on packaging (or as a packaging insert), or as instructions for

use. Consistent worldwide labelling requirements would offer significant benefits to the manufacturer, user and/or patient, and to Regulatory Authorities. To achieve this purpose, the following principles are recommended:

- As far as it is practical and appropriate, the information needed to identify and use the device safely should be provided on the device itself, and /or on the packaging for each unit, and / or on the packaging of multiple devices. If individual packaging of each unit is not practicable, the information should be set out in the leaflet, packaging insert or other media supplied with, or applicable to, one or multiple devices.
- Where the manufacturer supplies multiple devices to a single user and/or location, it may be sufficient and appropriate to provide with them only a single copy of the instructions for use. In these circumstances the device user should have access to further copies upon request.
- The medium, format, content, readability and location of labelling 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 require separate information for the healthcare professional and the lay user.
- Instructions may not be needed or may be abbreviated for devices of low or moderate risk if they can be used safely and as intended by the manufacturer without any such instructions.
- Labelling may be provided to the user in various media and by several means such as printed documents, through a display screen incorporated into the device, downloaded from the manufacturer's Web Site using the Internet, magnetic or optical media. Whatever the media or the means, information should be targeted to the anticipated user population.

Note: Some jurisdictions may provide conditions for the provision of electronic labelling, e.g. paper versions must be available to users as well as electronic ones.

- Any residual risk identified in the risk analysis should be reflected as contra-indications or warnings within the labelling.
- Country-specific requirements for labelling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.
- The use of internationally recognised (i.e. standardised) symbols should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the symbol is not obvious to the device user, e.g. for a lay-user or for a newly introduced symbol, an explanation should be provided.

Provided that safe and correct use of the device is ensured, a Regulatory Authority may authorise labelling to be in one or more language(s) other than its national language(s).

5.2 Content of Labelling

The labelling should bear the following particulars.

- a) The name or trade name and address of the manufacturer and, if appropriate, a phone number and/or fax number and/or website address to obtain technical assistance.

For imported devices, information may be required to contain in addition, the name and address of either the importer established within the importing country/region or of an authorized representative of the manufacturer established within the importing country/region.

- b) Sufficient details for the user to identify the device and, where these are not obvious, its intended purpose, user and patient population of the device; also, where relevant, the contents of any packaging.
- c) An indication of either the batch code/lot number (e.g. on single-use disposable devices or reagents) or the serial number (e.g. on electrically-powered medical devices), where relevant, to allow appropriate actions to trace and recall the devices.
- d) 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, single-use disposable devices or reagents), where this is relevant. Where relevant, the storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions.
- e) For devices other than those covered by (d) above, and as appropriate to the type of device, an indication of the date of manufacture. This indication may be included in the batch code/lot number or serial number.
- f) The information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature, and frequency of preventative and regular maintenance, where relevant any quality control, replacement of consumable components, and calibration needed to ensure that the device operates properly and safely during its intended life.
- g) Any warnings, precautions, limitations or contra-indications.
- h) The performance intended by the manufacturer and, where relevant, any undesirable side effects.
- i) An indication on the external packaging of any special storage and /or handling conditions that apply.
- j) Details of any further treatment or handling needed before the device can be used (e.g. sterilization, final assembly, calibration, preparation of reagents and/or control materials, etc.) where relevant.
- k) If the device is sterile, an indication of that condition and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization.
- l) If the device has been specified by the manufacturer as intended for single-use only, an indication of that state.
- 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 state.

- n) If the device is intended for premarket clinical investigation or, for *in vitro* diagnostic medical devices, performance evaluation, only, an indication of that situation.
- o) If the device is intended for presentation or demonstration purposes only, an indication of that situation.
- p) If the device is to be installed with or connected to other medical devices or equipment, or with dedicated software, in order to operate as required for its intended use, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.
- q) If the device is implantable, information regarding any particular risks in connection with its implantation.
- r) Information regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations, evaluations, treatment or use (e.g. electromagnetic interference from other equipment).
- s) 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 and any restriction on the number of reuses. Where a device is supplied with the intention that it is sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still perform as intended by the manufacturer and comply with the *Essential Principles of Safety and Performance of Medical Devices*.
- t) If the device is a reprocessed device, additionally the name of the reprocessor, and identification of the device as a reprocessed device.
- u) If the device emits radiation for medical purposes, details of the nature, type and where appropriate, the intensity and distribution of this radiation.
- v) Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

The instructions for use should also include, where appropriate, details informing the users and/or patient and allowing the medical staff to brief the patient on any contra-indications, warnings and any precautions to be taken. These details should cover in particular:

- w) Precautions and/or measures to be taken in the event of changes in the performance, or malfunction, of the device including a contact telephone number, if appropriate.
- x) Precautions and/or measures to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, temperature, humidity, acceleration, thermal ignition sources, proximity to other devices, etc.
- y) If the device administers medicinal products, adequate information regarding any medicinal product(s) which the device in question is designed to administer, including any limitations in the choice of substances to be delivered.

- z) Any medicinal substances or biological material incorporated into the device as an integral part of the device.
- aa) If the device has a measuring function, the degree of accuracy claimed for it.
- bb) Any requirement for special facilities, or special training, or particular qualifications of the device user and/or third parties
- cc) Any precautions to be taken related to the disposal of the device and/or its accessories (e.g. lancets), to any consumables used with it (e.g. batteries or reagents) or to any potentially infectious substances of human or animal origin.
- dd) Where relevant, for devices intended for lay persons a statement clearly directing the user not to make any decision of medical relevance without first consulting his or her health care provider.

And for in vitro diagnostic medical devices, in addition to the information required above, directions/instructions for the proper use of in vitro diagnostic medical devices which may include:

- ee) Intended use / purpose (e.g. monitoring, screening or diagnostic) including an indication that it is for *in vitro* diagnostic use.
- ff) Test principle.
- gg) Specimen type.
- hh) Conditions for collection, handling and preparation of the specimen.
- ii) Reagent description and any limitation (e.g. use with a dedicated instrument only).
- jj) 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.
- kk) Assay procedure including calculations and interpretation of results.
- ll) Information on interfering substances that may affect the performance of the assay.
- mm) Analytical performance characteristics, such as sensitivity, specificity, accuracy (which is a combination of trueness and precision).
- nn) Diagnostic performance characteristics, such as sensitivity and specificity.
- oo) Reference intervals.