# FINAL DOCUMENT

## Global Harmonization Task Force

**(revision of GHTF/SG1/N29:2005)**

**Title:** Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'

**Authoring Group:** Study Group 1 of the Global Harmonization Task Force

**Endorsed by:** The Global Harmonization Task Force

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This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

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.

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# Preface

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# 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 those regulatory means considered the most suitable.

The primary way in which the Global Harmonization Task Force (GHTF) achieves its goals is through the production of harmonized guidance documents suitable for implementation or adoption by member Regulatory Authorities, as appropriate taking into account their existing legal framework, or by nations with developing regulatory programmes. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This guidance document is one of a series that together describe a global regulatory model for medical devices. It provides a definition of a term that is used in all GHTF publications. The GHTF first published guidance on this subject in a document entitled *GHTF/SG1/N29:2005 Definition of the Term 'Medical Device'*.

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

- modify the definition of 'medical device';
- provide a definition for the term 'In Vitro Diagnostic (IVD) medical device';
- provide ancillary definitions for 'accessory to a medical device' and 'accessory to an IVD medical device' in Section 4.0 of the document; and
- clarify the 'Notes' within the document.

This document 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.

Regulatory Authorities that are developing regulations or amending existing ones are encouraged to consider the adoption of this guidance and the principles it embodies, as this will help to reduce the diversity of schemes worldwide and facilitate the process of harmonization.

This guidance document has been prepared by Study Group 1 of the Global Harmonization Task Force (GHTF). Comments or questions about it should be directed to the Chair of GHTF Study Group 1 whose contact details are available on the GHTF website[1].

# 2.0 Rationale and Scope

## 2.1 Rationale

The development of consistent, harmonized definitions for the terms 'medical device', and an 'In Vitro Diagnostic medical device', that could be used within a global regulatory model would offer significant benefits to the manufacturer, user, patient or consumer, and to Regulatory Authorities and support global convergence of regulatory systems. Eliminating

[1] www.ghtf.org

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

### 2.2 Scope

This document is intended to provide harmonized definitions of the terms 'medical device' and 'In Vitro Diagnostic (IVD) medical device'. These terms appear in guidance documents published by the Global Harmonization Task Force. Adopting the definitions from this document will allow a Regulatory Authority to identify the products subject to medical device regulatory controls.

This document is intended to serve as guidance for Regulatory Authorities, Conformity Assessment Bodies and the regulated Industry.

## 3.0 References

Not required for this document.

## 4.0 Definitions

**Accessory to a medical device:** means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use.

**Accessory to an IVD medical device:** means an article intended specifically by its manufacturer to be used together with a particular IVD medical device to enable or assist that device to be used in accordance with its intended use.

**Note:** Some jurisdictions include 'accessories to a medical device' and 'accessories to an IVD medical device' within their definitions of 'medical device' or 'IVD medical device', respectively. Other jurisdictions do not adopt this approach but still subject an accessory to the regulatory controls (e.g. classification, conformity assessment, quality management system requirements etc.) that apply to medical devices or IVD medical devices.

## 5.0 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'

### 5.1 Medical Device

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical 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 by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

**Note:** Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for.in-vitro fertilization or assisted reproduction technologies.

## 5.2 In Vitro Diagnostic (IVD) Medical Device

'In Vitro Diagnostic (IVD) medical device' means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

**Note 1:** IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

**Note2:** In some jurisdictions, certain IVD medical devices may be covered by other regulations.