FINAL DOCUMENT

Title: Information Document Concerning the Definition of the Term "Medical Device"

Authoring Group: GHTF Study Group 1

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 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 recognizes that some Regulatory Authorities may have to reflect different local needs when they define a medical device. However, Regulatory Authorities that are developing such a definition or amending an existing one are encouraged to consider the adoption of the system described in this document, as this will help to reduce the diversity of schemes worldwide and facilitate the process of harmonization.

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 page[1].

2.0 Rationale, Purpose and Scope

2.1 Rationale

The development of a consistent, harmonized definition for a 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 differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

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[1] www.ghtf.org

2.2 Purpose

To recommend to Regulatory Authorities a harmonized definition of a medical device, and provide information on products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach.

2.3 Scope

This document applies to products that have a medical purpose, including those used for the *in vitro* examination of specimens derived from the human body.

3.0 References

Not required for this document.

4.0 Definitions

Not required for this document.

5.0 Harmonized definition of the term "medical device"

'**Medical device'** means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
   - ξ diagnosis, prevention, monitoring, treatment or alleviation of disease,
   - ξ diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
   - ξ investigation, replacement, modification, or support of the anatomy or of a physiological process,
   - ξ supporting or sustaining life,
   - ξ control of conception,
   - ξ disinfection of medical devices,
   - ξ providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;

and

b) 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.

Note 1: The definition of a device for *in vitro* examination includes, for example, reagents, calibrators, sample collection and storage devices, control materials, and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device

may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, some *in vitro* diagnostic devices, including reagents and the like, may be covered by separate regulations.

Note 2: Products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,
- accessories for medical devices (see Note 3),
- disinfection substances,
- devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls.

Note 3: 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 procedures as apply to the medical device itself. For example, an accessory will be classified as though it is a medical device in its own right. This may result in the accessory having a different classification than the 'parent' device.

Note 4: Components to medical devices are generally controlled through the manufacturer's quality management system and the conformity assessment procedures for the device. In some jurisdictions, components are included in the definition of a 'medical device'.