



PROPOSED FINAL DOCUMENT

Title: Definition of the Terms “Medical Device” and “In Vitro Diagnostic (IVD) Medical Device”

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Preface

The document herein was produced by the Asian Harmonization Working Party, based on the Global Harmonization Task Force Final Document GHTF/SG1/N071: 2012 of GHTF Study Group 1. The document is intended to provide non-binding guidance for use in the regulation of medical devices including In Vitro Diagnostic (IVD) medical devices, and has been subject to consultation throughout its development.

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1.0 Introduction

The objective of the Asian Harmonization Working Party (AHWP) is to encourage convergence at the worldwide level in the evolution of regulatory systems for medical devices, including In Vitro Diagnostic (IVD) medical devices in order to protect the public health by those regulatory means considered the most suitable.

The primary way in which the Asian Harmonization Working Party (AHWP) 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 member economies with developing regulatory programmes. Eliminating differences between member economies 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 regulatory model for medical devices, including In Vitro Diagnostic (IVD) medical devices. It aims to provide a definition of a term that is used in all AHWP publications.

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.

Work Group 2 and Work Group 1 of the AHWP have prepared this guidance document. Comments or questions should be directed to the Chair of AHWP Work Group 2 and Work Group 1 whose contact details may be found on the AHWP web page (<http://www.ahwp.info/>).

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 worldwide recognized 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 member economies 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 Asian Harmonization Working Party. 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.

Note: Some member economies include 'accessories to a medical device' within their definitions of 'medical device'. Other member economies 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.

Accessory to an IVD medical device: means an article which, is intended specifically by its manufacturer to:

- be used together with an IVD medical device to enable that device to be used in accordance with its intended use as an IVD medical device.
- or to augment or extend the capabilities of that device in fulfilment of its intended use as an IVD medical device.

Note: An accessory to an IVD medical device should be treated as an IVD medical device for the purpose of regulatory controls (e.g. classification, conformity assessment, quality management system requirements etc.)

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, 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 or disability,
- 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 member economies but not in others include:

- disinfection substances,

- 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, including blood and tissue donations, solely or principally to provide information:

- concerning a physiological or pathological state;
- concerning a congenital abnormality;
- concerning the predisposition to a medical condition or a disease;
- to determine the safety and compatibility with potential recipients;
- to predict treatment response or reactions;
- to define or monitor therapeutic measures.

This includes kits, reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus, systems or other articles.

Note: Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for a particular in vitro diagnostic examination. (Refer to Annex 1 for examples)

Annex I

Examples of product of general laboratory use and IVD medical devices:

	Laboratory use product	IVD Medical Devices
Centrifuges	General centrifuges, cytospin	Hematocrite centrifuge
Pipettes	General purpose pipettes (e.g. single or multiple pipettes, plastic pipettes, Pasteur pipettes)	Blood coagulation pipettes with automatic timing (Accessory of coagulometer)
Tubes and flasks	Erlenmeyers, plastic tubes	Blood collection tubes, urine sample containers
Plates	Empty ELISA plates, empty Petri dishes	Coated microtiter plates for the diagnosis of Lyme's disease
Nucleic Acid extraction products	DNA and RNA extraction kits that only provide a specimen without an intended IVD detection combination	DNA and RNA extraction kits intended to provide a specimen to be used with an IVD device (validation for at least one combination is to be provided)
General equipment	Scales, balances, microtomes, incubators, sterilizers for laboratory equipment, paraffin embedding machine	
HPLC products	size-exclusion HPLC columns	HPLC columns for IVD purposes: e.g. HbA1c
Detection equipment	Mass spectrometer, spectrophotometers, ELISA readers providing raw data which is not readily readable and understandable by the user (e.g. peaks, OD).	McFarland bacteria density testing
Others	Foetal calf serum, cell culture media, fixation solution, mounting media, buffers (e.g. PBS), chemicals (e.g. sulphuric acid, formol, water)	

(This table contains a non-exhaustive list of examples).

