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PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Medical Devices Classification

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

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Preface

This document was produced by the Global Harmonization Task Force, a voluntary consortium of representatives from medical device Regulatory Authorities and trade associations from around the world. 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 and endorsement by the current Chair. Endorsement by the Chair signifies acceptance by consensus amongst members of the GHTF Steering Committee, as a document to be promoted by all members of the GHTF.

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 or by nations with developing regulatory programmes.

1.0 Introduction

The purpose of this document is to assist a manufacturer to allocate its medical device to an appropriate risk class using a set of harmonized rules. Regulatory Authorities have the responsibility of ruling upon matters of interpretation for a particular medical device. Subsequently, such classification will prescribe how the manufacturer will demonstrate that its device complies with the *Essential Principles for Safety and Performance of Medical Devices, Labelling for Medical Devices* and any other relevant controls, should it be required or requested so to do by a Regulatory Authority, Conformity Assessment Body, user or third party.

This document should be read in conjunction with the GHTF document on *Premarket Conformity Assessment for Medical Devices* that recommends conformity assessment requirements appropriate to each of the four risk classes identified herein. These inter-relationships are critical in establishing a consistent approach across all counties/regions adopting GHTF principles, so that premarket approval for a particular device is acceptable globally.

The GHTF believes that deviations from the premarket approval processes described in these two documents should be rare and will occur only in the following situations:

- Where through post-market experience, a level of risk for a type of medical device, classified using the criteria found in this guidance document is no longer appropriate, consideration should be given to re-classification by a change to the rules. This should be established in the relevant Global Harmonization forum and must be clearly desirable in the global sphere.
- Where through post-market experience, a level of risk for a particular medical device within a classification grouping is different from that allocated through the classification rules, a change to the rules may not be appropriate. In this case, a Regulatory Authority may, when sufficient justification is available, be flexible in the application of conformity assessment requirements in relation to this particular device, provided there is no increased risk to the health of the patient and/or user.
- When a medical device, or a grouping of medical devices classified using the criteria found in this guidance document, incorporates new technology, a change to the classification rules will normally be unnecessary. Instead, the Regulatory Authority and/or Conformity Assessment Body may require more stringent conformity assessment requirements to apply, at least until the use of such new technology or principles has been fully understood and post-market experience shows that there is no longer a need for such extra measures.

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 either the Chairman or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF web page.

2.0 Scope

This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Information Concerning the Definition of the Term "Medical Device"*, **other than those** used for the *in vitro* examination of specimens derived from the human body.

This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement. It is intended for use by medical devices 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 new classification schemes or amending existing ones are encouraged to consider the adoption of the system described in this guidance document, as this will help to reduce the diversity of schemes world-wide and facilitate the process of harmonization.

The regulatory requirements of some countries may not, at present, reflect the contents of this document.

3.0 References

Final documents

SG1/N009 *Labelling for Medical Devices*

Final documents that have been or are likely to be superseded

SG1/N012 *Role of Standards in the Assessment of Medical Devices.*

SG1/N020 *Essential Principles of Safety and Performance of Medical Devices*

Documents available for public comment at 5 October 2002

SG1/N011 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices.*

SG1/N029 *Information Document Concerning the Definition of the Term 'Medical Device'.*

SG1/N041 *Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices).*

SG1/N043 *Labelling for Medical Devices (including In Vitro Diagnostic Devices).*

Documents being prepared for public comment

SG1/N040 *Premarket Conformity Assessment for Medical Devices.*

4.0 Definitions

Active implantable medical device: means any active medical device, together with any accessories for its proper functioning, which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure. (Source - European Directive 90/385/EEC - with accessories included)

Active medical device: Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. (Source - European Directive 93/42/EEC)

Active therapeutic device: Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap. (Source - European Directive 93/42/EEC)

Active device for diagnosis: Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities. (Source - European Directive 93/42/EEC)

Central circulatory system: For the purpose of this document, `central circulatory system' means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, renal arteries and common iliac arteries.

Central nervous system: For the purpose of this document, `central nervous system' means brain, meninges and spinal cord. (Source - European Directive 93/42/EEC)

Duration of use

Transient: Normally intended for continuous use for less than 60 minutes.

Short term: Normally intended for continuous use for between 60 minutes and 30 days.

Long term: Normally intended for continuous use for more than 30 days.

NOTE: For the purpose of this document, continuous use means the uninterrupted actual use of the device for the purpose intended by the manufacturer, except where the reason for interruption is to replace a failing/failed device with one identical to it (e.g. replacement of a urinary catheter), where this should be regarded as an extension of continuous use.

(Source - European Directive 93/42/EEC)

Harm: Physical injury or damage to the health of people or damage to property or the environment. (Source – ISO/IEC Guide 51:1999)

Hazard: Potential source of harm. (Source – ISO/IEC Guide 51:1999)

Immediate danger: A situation where therapy is required as soon as possible after the abnormal condition is diagnosed in order to prevent serious harm to the patient.

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.

Invasive devices

Invasive device: A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice: Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

Surgically invasive device: An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

NOTE: Devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

Implantable device: Any device, including those that are partially or wholly absorbed, which is intended:-

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

(Source - European Directive 93/42/EEC)

Life supporting or life sustaining: A device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

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

Potentially hazardous manner: The potential of the device, when used as intended, to harm the patient due, for example, to the lack of direct oversight of the patient by a clinician or the high risk associated with the particular application of the device or the type of technology involved.

Reusable surgical instrument: Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out. (Source - European Directive 93/42/EEC – minor modifications)

Risk: Combination of the probability of occurrence of harm and the severity of that harm. (Source – ISO/IEC Guide 51:1999)

5.0 General Principles

Regulatory controls are intended to safeguard the health and safety of patients, users and other persons by ensuring that manufacturers of medical devices follow specified procedures during design, manufacture and marketing.

The risk presented by a particular device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use.

The GHTF guidance documents *Essential Principles of Safety and Performance of Medical Devices* and for *Labelling for Medical Devices* **apply to all device risk classes.**

Regulatory controls should be proportional to the level of risk associated with a medical device. The level of regulatory control should increase with increasing degree of risk, taking account of the benefits offered by use of the device. At the same time, the imposition of regulatory controls should not place an unnecessary burden on regulators or manufacturers.

Therefore:

- there is a need to classify medical devices based on their risk to patients, users and other persons; and
- there is benefit for manufacturers and Regulatory Authorities if a globally harmonized classification system is developed.

The risk presented by a device also depends, in part, on the degree of innovation in a device, its intended use, its intended user(s), its mode of operation, and/or technologies. In general, the classification rules are intended to accommodate such innovations. Without prejudice to these rules, Regulatory Authorities may wish to require the notification of new devices being placed on the market in their jurisdictions. Such notification may be used in assessing the evidence requirements for use in the conformity assessment process. It may also be used to consider the need, if any, for possible re-classification and/or changes in the harmonized classification rules.

6.0 Recommendations

6.1 Primary Recommendations

- Regulatory Authorities should work towards the establishment of a global classification system.
- Such a system should be based upon common features of existing national requirements with the aim of future convergence.
- This system should consist of four risk classes. Based on experience of GHTF Founding Members, this is sufficient to accommodate all medical devices and allows an efficient and graduated system of conformity assessment controls.
- The determination of class should be based on a set of rules derived from those features of devices that create risk.
- The set of rules should be sufficiently clear that manufacturers may readily identify the class of their medical devices, subject, when appropriate, to confirmation by the Regulatory Authority.
- The manufacturer should document its justification for placing its product into a particular risk class, including the resolution of any matters of interpretation where it has asked a Conformity Assessment Body and/or Regulatory Authority for a ruling.
- The rules should be capable of accommodating future technological developments.
- Regulatory Authorities should consult with the Global Harmonization Task Force, their international counterparts and industry if considering changes to the rules or other classification issues.
- Any exceptions to the classification rules introduced by a Regulatory Authority to reflect and implement national health policy within its own jurisdiction should be minimised and eliminated in the long term.