GUIDANCE NOTES FOR MANUFACTURERS OF CLASS I MEDICAL DEVICES

Foreword

These guidance notes do not aim to be a definite interpretation of National Laws and/or regulations and are for guidance purpose only. This document should be read in conjunction with the relevant guidance listed in Annex A including the new guidance produced by MSOG for manufacturers of custom made devices.

National Enforcement Authorities are bound by their own legislation and can only apply this guidance within the confines of their own law.

Introduction

The purpose of this document is to provide guidance to Class I medical device manufacturers or their Authorised Representative who place medical devices on the European Market under the manufacturer's name, to help them to meet the requirements of national legislation that transposes the Medical Devices Directive 93/42/EEC ("MDD") (latest amended by directive 2007/47/EC)

National legislation transposing the amendments introduced by directive 2007/47/EC will come into force 21st March 2010.

All medical devices must comply with the essential requirements established in Annex I of the MDD, ensuring that they do not compromise the health and safety of patients, users and any other person and perform as intended by the manufacturer. Medical Devices bear the CE mark to indicate their conformity with the MDD.

The manufacturer or Authorised Representative, shall follow the procedure referred to in Article 11.5 and Annex VII and draw up the EC declaration of conformity required before placing their products on the market.

Definitions

Accessory – an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device *(Ref.: MDD; Article 1 (2) (b))*

Authorised Representative – Any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under the Directive. *(Ref.: MDD; Article 14 (2) (j))*

Where a manufacturer who places a device on the market under his own name does not have a registered place of business in a Member State, he shall designate a single authorised representative in the European Union (Article 14 (2)). This will ensure that authorities have a single indi-

vidual person, authorised by the manufacturer, whom they can address in matters relating to the compliance of the devices with the Directives. The designation should be effective at least for all devices of the same model.

Class I medical devices with measuring function - are considered Class l medical devices which measure physiological parameters or energy, respectively, substances delivered to or removed from the body and display or indicate its value in a unit of measurement (example: urine bags or thermometers).

Conformity Assessment – The process to verify the conformity of a medical device with the essential requirements. This process depends on the medical device classification, according to the procedures described in the MDD.

Harmonised Standards - are European Standards prepared under a mandate from the European Commission and referenced in the Official Journal. Compliance with harmonised standards provides presumption of conformity to the corresponding essential requirement of the MDD.

Intended use/intended purpose – use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer.

Medical Device - means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (Ref.: MDD; Article 1 (2) (a))

The definition of a medical device has been amended to clarify that it includes software intended to be used specifically for diagnostic and/or therapeutic purposes.

Manufacturer – The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under their own name, regardless of whether these operations are carried out by that person or on their behalf by a third party.. (Ref.: MDD; Article 1 (2) (f)). See guidance on Own Brand Labelling on Commission website.

Placing on the market of Class I medical devices: The necessary steps

Manufacturers or their Authorised Representatives that intend to place Class I medical devices on the market should follow the procedures mentioned below.

Step 1 – Confirm product as a medical device

Confirm that the product comes within the definition of a medical device as defined in Article 1 (2) of the MDD as amended in accordance with its principal intended purpose and mode of action. There will of course be borderline products where such a determination could be difficult, in such cases consult the relevant Competent Authority for advice.

Step 2 - Confirm product as a Class I medical device

Consult Annex IX of the MDD to confirm that the product is correctly classified as Class I.
The application of the classification rules shall be governed by the intended purpose of the device and the time of use, part of the body, whether it is active or not, whether it is invasive or non-invasive.

If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use. In other words if a device could be classified using different rules then the final classification will be the highest.

Step 3 – Procedures before the Placing on the Market

3a – Meet the Essential Requirements

The devices must meet the essential requirements set out in Annex I of the Directive which apply to them, taking account of the intended purpose of the devices concerned. Devices must be designed and manufactured in such a way that, when used under normal conditions of use and for the purposes intended by the manufacturer, they will not compromise the clinical condition or the safety of patients or the safety and health of users or other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. The devices must achieve the performance as intended by the manufacturer.

3b – Prepare technical documentation

The manufacturer or his authorised representative must hold technical documentation that demonstrates the conformity of their products with the requirements of the Directive. This technical documentation must be prepared prior to drawing up the EC declaration of conformity and kept available for review by the Competent Authority. Manufacturers should also check with the Competent Authority as to the language requirements for such information.
The technical documentation should be prepared following review of the essential requirements and other relevant requirements of the Directive and must cover all of the following aspects.

• *DESCRIPTION. A general description of the product, including any variants (for example names, model numbers addition of medicinal substances and sizes).*

• *RAW MATERIALS AND COMPONENT DOCUMENTATION. Specifications including, as applicable details of raw materials, drawings of components and/or master patterns and any quality control procedures.*

• *INTERMEDIATE PRODUCT AND SUB-ASSEMBLY DOCUMENTATION.*
Specifications, including appropriate drawings and/or master patterns, circuits, and formulation specifications; relevant manufacturing methods; and any quality control procedures.

• *FINAL PRODUCT DOCUMENTATION. Specifications, including appropriate drawings, and/or master patterns, circuits, and formulation specification; relevant manufacturing methods; justification for choice of materials and any quality control procedures.*

• *PACKAGING AND LABELLING DOCUMENTATION. Packaging specifications and copies of all labels and any instructions for use.*

• *DESIGN VERIFICATION. The results of qualifications tests and design calculations relevant to the intended use of the product, including connections to other devices in order for it to operate as intended. If the manufacturer can provide information showing that a safe design has been established for a number of years and that product has been performing as intended during that time such information is likely to be sufficient to cover this requirements.*

• *RISK MANAGEMENT. The results of risks analysis to review whether any risk associated with the use of the product are compatible with high level of protection of health and safety and are acceptable when weighed against the benefits to the patient or user. If biocompatibility is relevant, for example for skin contact and invasive devices, a compilation and review of existing data or test reports based on the relevant standards is required.*

• *COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS AND HARMONISED STANDARDS. A list of relevant harmonised standards (for example sterilisation, labelling and information, biocompatibility, electrical safety, risk analysis, product group standards) which have been applied in full or in part of the products. If relevant harmonised standards have not been applied in full, then additional data will be required detailing the solutions adopted to meet the relevant essential requirements of the Directive. In addition any sterilisation descriptions should be listed.*

• *CLINICAL DATA. Many class I devices will not require a special clinical investigation to establish data on performance and safety or side effects. For products which have been established for a number of years and those which are modifications for such products, it is likely that a compilation and review of existing clinical experience would be sufficient to cover this requirement. However all manufacturers should review the intended use of the product and any medical claims that are being made to ensure that they have both adequate supporting test results and records of relevant experience. However as a general rule confirmation of conformity with the requirements concerning characteristics and performance of the device under the normal conditions of use including undesirable side effects should be based on clinical data.*

Only in a minority of cases will a specifically designed clinical investigation be necessary in order to demonstrate device safety and performance as required by the Directive. Note that if a clinical investigation is required to justify the use of a device, then the Competent Authority requires advance notification of the proposal.

After 21 March 2010 the Directive will include a requirement that evaluation of clinical data must follow a defined and methodologically sound procedure based on (Ref MDD Annex X)

- *Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:*
  - *there is demonstration of equivalence of the device to the device to which the data relates, and*
  - *the data adequately demonstrate compliance with the relevant essential requirements.*
- *Or a critical evaluation of the results of all clinical investigations made.*
- *Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2*

• *OVERLAP WITH PPE DIRECTIVE (comes into force 21 March2010)*

Article 1 (6) of the Directive requires that products which are placed on the market by the manufacturers as dual purpose products being PPE as well as a medical device shall also fulfil the relevant basic health and safety requirements of directive 89/686/EEC. A manufacturer who wishes to place his product on the market with the "dual purpose" must verify compliance with both those directives. Further guidance is available at the Commission homepage: "INTERPRETATION OF THE RELATION BETWEEN THE REVISED DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES AND DIRECTIVE 89/686/EEC ON PERSONAL PROTECTIVE EQUIPMENT"

• *OVERLAP WITH MACHINERY DIRECTIVE (comes into force 21 March 2010/29 December 2009)*

Article 3 of the Directive states that where relevant hazards exist medical devices which are also machinery, as defined in the Machinery Directive, should also meet the requirements of the Machinery Directive where its health and safety requirements are more specific than those in the essential requirement of the Medical Devices Directive. Again the Commission have provided detailed guidance on their website on this overlap: "INTERPRETATION OF THE RELATION BETWEEN THE REVISED DIRECTIVE 93/42/EECCONCERNING MEDICAL DEVICES AND DIRECTIVE 2006/42/EC ON MACHINERY".

Specific transitional guidance (See also: INTERPRETATIVE DOCUMENT OF THE COMMISSION'S SERVICES IMPLEMENTATION OF DIRECTIVE 2007/47/EC AMENDING DIRECTIVES 90/385/EEC, 93/42/EEC AND 98/8/EC):
The new Machinery Directive does not exclude medical devices and shall apply where the hazards referred to in its essential requirements are not covered by more specific requirements in other Community directives. During the period between the date of application of the Machinery Directive (29 December 2009) and of the revised Medical Devices Directives (21 March 2010), manufacturers can choose

- *to fully comply with the Machinery Directive and with the relevant Medical Device Directive,*
- *to comply with all new requirements of the revised Medical Devices Directives or*
- *to anticipate only compliance with the relevant EHSR of the Machinery Directive while otherwise complying with the requirements of the current relevant Medical Device Directive, including the usual regime regarding change control*

As of 21 March 2010, the Machinery Directive will cease to apply and the device will be subject to the revised Medical Devices Directives.

• *RECORDS. Manufacturing and test records to show compliance with the defined procedures and specifications. The manufacturer or his authorised representative must hold the documentation for at least five years after the product has been manufactured (Ref: MDD Article 12 (4), Annex II (6.1), Annex VII (2))*

3c – Request Notified Body intervention

In the case of products placed on the market in sterile condition the manufacturer or his authorised representative must follow the procedure referred to in Annex II or V of the MDD. For devices with a measuring function the manufacturer or his authorised representative must follow one of the procedures referred to in Annex II, IV, V or VI of the MDD. This requires the intervention of a notified body. In all other cases the intervention of a Notified Body is not required for Class I devices

The intervention by the notified body is limited to:

- in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions;
- in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

3d – Prepare Instructions for Use and Labelling

Each device must be accompanied by the information needed to use it safely and to identify the manufacturer or authorised representative, taking account of the training and knowledge of the potential users. This information comprises the label and the data in the instructions for use. By way of derogation to the general principles no instructions for use are required for Class I devices if they can be used safely without such instruction. Such devices could include bandages, ready made spectacles and walking sticks.

National language requirements must be taken into account in relation to the labelling and instructions for use. Language versions used are to be included in the technical documentation.

In the light of technical progress in information technology and medical devices, a process should be provided to allow information by the manufacturer also to be available by other means.

Step 4 – Draw-up the EC Declaration of Conformity

The EC declaration of conformity is the procedure whereby the manufacturer or the authorised representative, who fulfils the obligations imposed by Section 2 of Annex VII of the MDD and, in the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by Section 5 of Annex VII ensures and declares that the products concerned meet the provisions of this Directive which apply to them. The declaration of conformity should contain all information to identify the Directives to which it is issued, as well as the manufacturer, the authorised representative, the Notified Body and the product, and where appropriate a reference to harmonised standards or other relevant documents.

Step 5 – Affix the CE marking

All Class I medical devices placed on the market must bear the CE marking of conformity, which must be affixed in a visible, legible and indelible form on the device or in its sterile packaging, where practicable and appropriate, and on the instructions for use, as well as on any sales packaging.

In the case of Class I medical devices placed on the market in a sterile condition and/or devices with measuring function, the CE marking must be accompanied by the identification number of the relevant Notified Body.

It is prohibited to affix marks which are likely to mislead third parties with regard the meaning of the CE mark. Other additional marks may be affixed to the device, to the packaging or the instructions for use provided the visibility or legibility of the CE mark is not impaired.

The CE marking format should be in compliance with Annex XII of the MDD. Where the device is very small the minimum dimensions of the CE mark may be waived.

Step 6 – Notify the Competent Authorities

Under Article 14, the manufacturer of a Class I medical device, or his authorised representative, must inform the Competent Authority of the country in which they have their registered place of business of the address of the registered place of business and provide a description of the device that is sufficient to identify it. Manufacturers or his authorised representative should contact their relevant Competent Authority with regards the procedures and forms required for such notifications and whether a fee will apply.

Step 7 – Record, evaluate and notify incidents

The manufacturer or his authorised representative is responsible for activating the vigilance system and must inform the surveillance authority about incidents that invoke it according to Paragraph 4, Annex VII of the MDD. After notification, the manufacturer is obliged to make investigations, compile and send a report to the surveillance authority, and consider, in collaboration with the authority, what action should be taken. Directive 2007/47/EC will make it a requirement to notify all relevant Competent Authorities of adverse incidents occurring as part of a Clinical Investigation

Step 8 – Review experience gained from Post-Market Surveillance

The manufacturer shall put in place and keep updated a procedure to review experience gained from devices on the market and to implement necessary corrective action taking account of the nature and risks in relation to the product. Any clinical evaluation and its documentation must be actively updated with data from post market surveillance (Ref: Directive 2007/47/EC)

Annex 1

Information for manufacturers of medical devices can be found in the following sources:

- Medical Device Directive, 93/42/EEC of 14 June 1993 (last amended by 2007/47/EC).

- Guidelines for Vigilance System: "Guidelines on a Medical Devices Vigilance System" MEDDEV 2.12/1 Rev. 5 April 2007.

- Guideline for evaluation of Clinical Data: "Guidelines on Medical Device – Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies", MEDDEV 2.7/1 April 2003.

- Guidelines on Post Market Clinical Follow-up MEDDEV 2.12.2 May 2004

- Guideline for classification: "Guideline for the classification of medical devices", MEDDEV 2.4/1, Rev 8, July 2001.

- Guideline for medical device with a measure function: "Guidelines related to the application of: the Council Directive 90/385/EEC on Active Implantable Medical Devices, the Council Directive 93/42/EEC on Medical Devices – Medical devices with a measure function). MEDDEV 2.1/5 June 1998.

- Guidelines that explain the demarcation with other European Directives – medical devices/medicinal products: "Guidelines relating to the application of: the Council Directive 90/385/EEC on active implantable Medical Devices; the Council Directive 93/42/EEC on medical devices", MEDDEV 2.1/3, Rev 2, July 2001.

- Guideline for definitions of "medical devices", "accessory" and "manufacturer": "Guidelines related to the application of: the Council Directive 90/385/EEC on Active Implantable Medical Devices, the Council Directive 93/42/EEC on Medical Devices", MEDDEV 2.1/1 April 1994

- Interpretation of the relation between the revised Directive 93/42/EEC concerning Medical Devices and Directive 2006/42/EC on Machinery

- Interpretation of the relation between the revised Directive 93/42/EEC concerning Medial devices and Directive 89/686/EEC on Personal Protective Equipment

- Interpretation of the Medical Device Directives in relation to Medical Device Own Brand Labellers 4 February 2008-08-29

- Regulation of the European Parliament and of the Council setting out the requirements for accreditation and Market Surveillance relating to the marketing of products and repealing regulation (EEC) No 339/93: 9th July 2008

- Decision on the European Parliament and of the Council on a common framework for the marketing of products, and repealing decision 93/465/EEC: 9th July 2008

- Guide to the implementation of directives based on the New Approach and Global Approach.

- National authorities web sites,

- European Commission's web site.