# GUIDANCE NOTE FOR MANUFACTURERS OF CUSTOM-MADE MEDICAL DEVICES

## Foreword

This guidance document is informative and advisory and has no legal authority. Individual national enforcement authorities are bound by their own legislation and can only apply this guidance within their confines.

Only the text of the Directives is authentic in law. The text of the Directives is applicable where there are differences between the provisions of the Directives and the contents of this guide. The interpretation of Community law is ultimately the responsibility and the privilege of the European Court of Justice (ECJ). Any legal analysis set out in this guide does not in any way preclude a different interpretation by the ECJ in a particular case, and does not in any way commit the European Commission.

## Introduction

A manufacturer of a custom-made medical device, who places devices on the European market under his own name, must meet the requirements of national legislation, which transposes the Medical Devices Directive 93/42/EEC (MDD)[1].

Custom-made medical devices must comply with the relevant essential requirements established in annex I of the MDD to ensure that they do not compromise the health and safety of patients, users and any other persons. Whenever this is impossible, the manufacturer must indicate which of the essential requirements has not been fully met.

Manufacturers of custom-made medical devices shall follow the procedure referred to in annex VIII and draw up the EC declaration of conformity before placing them on the market.

## Scope

This guidance document deals specifically with custom-made medical devices as defined in the MDD. The scope of this guidance document is to provide general guidance for manufacturers of custom-made medical devices in order meet the requirements of MDD.

In relation to manufacturers who do not have a registered place of business in the European Community, article 14 of the MDD requires the manufacturer to designate an authorised representative to be their legal representative within the Community.

[1] Note: This guidance note refers to the MDD version OJ 169 / 12.07.93

## 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 latter's obligations under the Directive. *(Ref.: MDD; Article 1 (2) (j))*

*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.

*Custom-made manufacturer* – The natural or legal person who undertakes the design of the product and manufactures the device to a predefined specification (i.e. a prescription).

*Custom-made medical device* - Any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. *(Ref.: MDD Article 1 (2) (d))*

*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 his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The obligations of the Medical Device Directives to be met by manufacturers also apply to the natural or legal person who assembles, package, processes, fully refurbishes and / or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This sub-paragraph does not apply to the person who, while not a manufacturer within the meaning of the first sub-paragraph, assembles or adapts devices already on the market to their intended purpose for an individual patient. *(Ref.: MDD Article 1 (2) (f)*

*Medical device* – 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))*

*Risk* – Combination of the probability of occurrence of harm and the severity of that harm.

*Risk management* – Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risk.

# Placing on the Market of Custom-Made Medical Devices - The Necessary Steps

Manufacturers that intend to place custom-made medical devices on the market should follow the procedures mentioned below which are also summarised in the attached flowchart (annex A).

**Step 1 – Confirm product as a medical device**

Manufacturers must confirm if the product is in compliance with the medical device definition according to is principal intended use and mode of action.

The European Commission MEDDEV 2.1/1 and 2.1/3 Rev 2 should be consulted.

**Step 2 – Confirm products as a custom-made medical device**

A custom-made medical device is a device that is manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner who gives, under his responsibility, specific characteristics as to its design, and that it is intended for the sole use of a particular patient.

It should be noted that mass produced devices which need to be adapted to meet the specific requirements prescribed by the healthcare professional, are not considered to be custom-made medical devices. For example, glasses or corneal lenses which are CE marked and prescribed for a patient under a written prescription are not deemed to be custom made medical devices as they are mass produced and subsequently adapted to suit the needs of the individual patient.

Custom-made medical devices (such as dental appliances, prosthesis, hearing-aid inserts) are in most cases one-off devices. In these instances intermediate products specifically intended for these kind of custom-made devices may be also be considered as medical devices. This applies essentially to dental alloys, dental ceramics, modular components for prosthesis, if the intended purpose of such products is specifically related to medical devices.

**Step 3 - Procedures before the placing on the market**

Custom-made medical device manufacturers should guarantee that specific characteristics of their custom-made medical devices are in accordance with all the applicable requirements of the MDD and related relevant harmonised standards.

Manufacturers of custom-made medical devices must consider the following steps, with reference to the Essential Requirements described in Annex I, and to Annex VIII of the MDD.

***Step 3a – Meet the essential requirements***

Manufacturers of custom-made medical devices meet the essential requirements as listed in Annex I of the MDD.

Such essential requirements cover amongst others:

- handling and packaging of devices;

- materials choice (e.g. with regard to toxicity, when there is patient contact, CE marked materials should be used or the manufacturer must guarantee the suitability of the materials by other means);
- manufacturing under controlled conditions;
- cleanliness and cross infection control;
- protection against radiation;
- requirements for medical devices connected to or equipped with an energy source;
- information to be supplied by the manufacturer

***Step 3b – Prepare technical documentation***

To comply with the MDD, manufacturers of custom-made medical devices, or their designated authorised representatives, must follow the procedure referred to in Annex VIII, Point 3.1 of the MDD.

This procedure includes preparing technical documentation, allowing an understanding of the design and manufacturing process, including the expected performance of the product, so as to allow assessment of conformity of the product with the MDD requirements.

The manufacturer must take all the necessary measures to ensure that the manufacturing process is in accordance with the technical documentation.

The technical documentation prepared should be appropriate to the complexity of the particular custom-made medical device.

The technical documentation, which should be prepared for custom-made medical devices typically includes:

***Design, manufacturing and product performance records, which may consist of:***

**1.** Name, trademark and category of the device, if applicable;
**2.** General description of the product, including any variant;
**3.** Rational for classification;
**4.** Indication if it is a sterile device;
**5.** If the device incorporates a medicinal product, an animal tissue or a human blood stable derivative documentation relating to these aspects;
**6.** Intended use, indications for use and contra-indications references if the device is to be connected to other devices in order to operate as intended;
**7.** Design drawings and specifications of the device, where applicable;
**8.** Specifications of the raw material, components, intermediate products / sub-assembles and final product;
**9.** Manufacturing methods;
**10.** Packaging specifications;
**11.** If it is a sterile device, description of the methods used and the standards applied;
**12.** Validation data in form of a reference to similar processes of serial produced devices;
**13.** Personnel's qualification data;
**14.** Design verification and quality control procedures;
**15.** Equipment used to monitor and control the raw materials, components and the final product, where applicable;

**16.** List of the standards referred to in article 5 of the MDD, applied in full or in part, and descriptions of the adopted solutions to meet the essential requirements of the MDD if the standards referred to in article 5 have not been applied.
**17.** Results of risk management per product family
**18.** Biocompatibility tests, if applicable;
**19.** Clinical data, if applicable;
**20.** Labelling and the instructions for use;
**21.** Name and the address of the subcontractors, if applicable;
**22.** A copy of the medical practitioner's prescription;
**23.** Procedures to ensure a review of the qualified persons written prescription in order to ensure that adequate information has been supplied and to document the manufacturing requirements;
**24.** Procedures allowing verification that the final product had been reviewed against the prescription, prior to placing the products on the market;
**25.** Procedures which guarantee the traceability from the manufacturer, through the practitioner to the patient.

***Step 3c– Risk management***

The use of a medical device entails some degree of risk. Manufacturers should make judgements relating to the safety of a medical device including the acceptability of risks, taking into account the generally accepted state of the art, in order to determine the probable suitability of a medical device to be placed on the market for its intended use.

Manufacturers shall establish and maintain a process, as outlined in Annex 1 of the MDD, for identifying hazards associated with their custom-made medical device, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of that control.

This process shall be documented as part of the technical documentation and should include the following elements:

- risk analysis (intended use identification, hazards identification, risk estimation);
- risk evaluation (risk acceptability decisions);
- risk control (protective measures for reducing risks to specified levels);
- post-production information (post-production experience and review of risk management experience).

The risk management may be based on ISO 14971 and be appropriate to the complexity and risk of the device.

***Step 3d – Prepare instructions for use and labelling***

As per point 13 of Annex I of the MDD, each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the label and the data in the instructions for use. In relation to custom-made medical devices, these instructions may be incorporated into the statement document referred to in step 4 below.

The minimum requirements regarding the labelling of a custom-made device should include:

- the name or trade name and address of the manufacturer. In addition, for devices imported into the European Community the name and address of either the person responsible referred to in article 14.2 of the MDD or of the authorised representative of the manufacturer established within the Community or of the importer established in the Community as appropriate; *(Ref.: MDD; Annex I.II 13.3(a))*

- the details strictly necessary for the professional to identify the device and the contents of the packaging (e.g. patient name/description); *(Ref.: MDD; Annex I.II 13.3(b))*

- the words "custom-made"; *(Ref.: MDD; Annex I.II 13.3(g))*

Other key requirements include:

- if appropriate, any special storage and/or handling conditions; *(Ref.: MDD; Annex I.II 13.3(i))*

- if appropriate, any warnings and/or precautions to take. *(Ref.: MDD; Annex I.II 13.3(k))*

*Note:* All the specified information in step 3 above should be kept for a period of not less than five years from the date of placing on the market of the custom-made medical device

**Step 4 – Draw up a statement concerning custom-made devices**

As per point 2 of Annex VIII of the MDD, manufacturers of custom-made medical devices must draw up a statement of for each custom-made device. The statement must contain the following information:

- Data allowing identification of the device in question, i.e. description, serial number, order number, generic name.

- Name of the manufacturer

- A statement that the device is intended for exclusive use by a particular patient together with the name of the patient (this may be an identification number if patient confidentiality needs to be maintained, provided it can be traced through records to the patient name).

- The name of the medical practitioner or other authorised person who made the prescription and, where applicable, the name of the clinical concerned,

- The particular features of the device as specified in the relevant prescription.

- A statement that the device conforms to the essential requirements set out in MDD Annex I, and where applicable, indicating which essential requirements have not been fully met, together with the grounds.

Article 4 of the MDD states that custom-made devices that fall into class IIa, IIb and III shall be accompanied by the statement referred to above.

The above statement must be drawn up before placing each device on the market. It should also be noted that Member States may require that the manufacturer shall submit to the CA a list of such devices which have been put into service in their territory.

**Step 5 – Notify the Competent Authorities**

Manufacturers of custom-made medical devices, or their designated authorised representative, must notify the Competent Authority in the Member State where they have a registered place of business, and provide a description of the devices concerned and the business address. A list of Competent Authority contact points can be found on the EU Commission website at http://ec.europa.eu/enterprise/medical_devices/ca/list_ca.htm. Manufacturers / authorised representatives should contact their relevant Competent Authority with regards the procedures and forms required for such notifications and whether or not a fee will apply.

**Step 6 – Incident reporting**

There is currently no legal requirement in the MDD for manufacturers of custom-made medical devices to report incidents, serious or otherwise, to the Competent Authority. However it is best practice for manufacturers of custom-made medical devices to report any adverse incidents with their custom-made medical devices.

*Note:* Manufacturers of custom-made medical devices may be required under specific National legislation to report incidents in accordance with the jurisdiction of their registered place of business.

**Step 7 – Review experience gained from post-market surveillance**

It is not a requirement of the MDD but it is advisable that manufacturers have in place a procedure to review experience gained from their custom-made medical devices on the market and to implement necessary corrective action taking account of the nature and risks in relation to the product.

**NOTE 1: The role of Competent Authority**

The Competent Authority has the authority to check control systems to ensure conformity with annex VIII.

**NOTE 2: CE marking**

Custom-made devices shall not be CE marked as specified in article 17 of the MDD. However manufacturers of custom-made devices must meet the essential requirements outlined in Annex 1 of MDD.

## Annex I: Further Information

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

- Medical Device Directive, MDD, 93/42/EEC of 14 June 1993. OJ L 169, 12.7.1993, p. 1, as last amended by Regulation (EC) No 1882/2003, OJ L 284, 31.10.2003, p.1.

- 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.

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

- 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.

- National authorities web sites

- European Commission's web site.

**Annex II –** Guidance Flowchart for Manufacturers of Custom-Made Medical Devices