HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide for
Custom-Made Dental Device Manufacturers on Compliance with European Communities (Medical Devices) Regulations, 1994

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

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1 SCOPE

This guidance document provides a general overview of requirements for manufacturers of typical custom-made dental devices. Examples of such devices include dentures, crowns and bridges. The legislation referred to below should be consulted to ensure that the device complies with all of the legislative requirements.

Custom-made devices for clinical investigation and the requirements for authorised representatives of custom-made manufacturers outside the EU are not within the scope of this guidance document.

2 INTRODUCTION

Dental devices specifically made for a particular named patient are classified under the European Communities (Medical Devices) Regulations, 1994, as amended, as 'custom-made' medical devices. It is important that manufacturers of custom-made dental devices are aware of the requirements of these regulations.

The Health Products Regulatory Authority (HPRA) is the Competent Authority for all medical devices including custom-made dental devices. The HPRA acts on behalf of the Irish government to ensure that the requirements of the Regulations are carried out and in doing so do not compromise the health and safety of patients, users and any other persons. The purpose of this guide is to provide a set of guidelines to enable manufacturers of custom-made dental devices to meet the requirements.

3 LEGISLATION

The following Irish legislation applies to custom-made dental devices:

- S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994, (transposed from Directive 93/42/EEC into Irish law).

This legislation was amended and should be read in conjunction with the above:

- S.I. No. 444 of 2001 European Communities (Medical Devices) (Amendment) Regulations, 2001.
- S.I. No. 576 of 2002 European Communities (Medical Devices) (Amendment) Regulations, 2002.
- S.I. No. 110 of 2009 European Communities (Medical Devices) (Amendment) Regulations, 2009.

Manufacturers of custom-made medical devices are recommended to pay particular attention to S.I. No. 110 of 2009 which includes amendments to legislation in relation to custom-made medical devices, in particular the amendments to Schedule 10.

4 DEFINITIONS

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 legislation.

Competent Authority
The Competent Authority is the body which has the authority to act on behalf of the government of a Member State to ensure that the requirements of the medical devices directives are carried out in that particular Member State. The role of the Competent Authority is determined by the directives and consequent national regulations. The primary role of the Competent Authority is to ensure that all medical devices sold on the Irish market meet the essential requirements of the directives and in doing so do not compromise the health and safety of patients, users and where appropriate, any other persons.

Custom-made
Custom-made means, in relation to a device:

a) that it is manufactured specifically in accordance with a written prescription of a registered medical practitioner or a professional user who gives, under his/her responsibility, specific characteristics as to its design and
b) that it is intended to be used only for a particular named patient
c) but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the registered medical practitioner or professional user.

In the manufacturing cycle of a 'custom-made' dental device, it is considered that it is the dentist who undertakes the design of the product and the dental laboratory that manufactures it to a predefined specification. It is also considered that if the manufacturer has manufactured the device to the prescribed requirements of the professional, the device should, if the professional has supplied the correct information, be fit for its intended purpose and not harm the clinical condition of the patient.

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.

Medical device
Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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.

5 MEETING THE REQUIREMENTS OF THE LEGISLATION

5.1 Registration

Manufacturers of custom-made medical devices in Ireland must register their custom-made medical devices and registered address with the Health Products Regulatory Authority. Please use the contact details provided at the end of this document in order to fulfil this registration requirement.

5.2 CE mark

Manufacturers of custom-made devices do not have to place the CE mark on such devices.

5.3 'The Essential Requirements' and Schedule 8 of the Regulations

All manufacturers of custom-made devices must comply with Schedule 1 (known as the Essential Requirements) and Schedule 8 of S.I. No. 252 of 1994, as amended. If any of the Essential Requirements are not fully met, the specific parts and reasons for not complying should be justified.

Requirements that apply to a manufacturer of a typical custom-made dental device include the following:

- Manufacturers of custom-made devices must keep documentation describing the design, manufacture and performances of the product. Design information may be provided on the device prescription. This may be requested for review by the HPRA.

- Manufacturing must be performed under controlled conditions e.g. following defined/documented processes and have some method of demonstrating they are being followed (e.g. records/work instructions which can be used to show traceability). Where

appropriate, equipment calibration and maintenance should be undertaken and records of such maintained.

- Relevant personnel within the laboratory should be suitably qualified and training records maintained.

- The device must be designed and manufactured in such a way as to reduce the risks posed by the device to the patient e.g. substances leaking from the device, risk of injury from the device. The intended patient should be considered and any special precautions taken e.g. pregnant women, children, or people with physical disabilities. These risk reductions should be formally recorded in a risk assessment document.

- The choice of materials should be considered e.g. with regard to toxicity. Where there is patient contact, CE-marked materials should be used or, if not, the manufacturer must guarantee the suitability (including biocompatibility) of the materials by other means.

- Clinical data should be available to support the device to demonstrate that the device does not compromise the safety or health of patients and performs as intended. This clinical evaluation should be documented by the manufacturer and may be reviewed by the HPRA. The clinical data review by the manufacturer may be done through:
  - a review of data already available for an equivalent device on the market
  - an assessment of the risks associated with the device and controls in place to mitigate against these risks
  - a review of information received from patients after use of the product (e.g. complaints, product recalls, periodic reviews)
  - a combination of all of the above, or any other means appropriate.

- Cleanliness and cross-infection controls within the laboratory should be adequate.

- The device should be handled and packaged in such a way to protect the device from any damage for example during storage or transport.

5.4 Information provided with finished devices

Each finished device should be accompanied by information supplied by the manufacturer to use and maintain the device properly, taking into account the training and knowledge of potential users. No such instructions for use are required for low risk devices that can be used safely and cleaned without instruction or precautions.

The label of a custom-made dental device must include:
- the name or trade name and address of the manufacturer or authorised representative as appropriate
- the details necessary for the professional to identify the device and the contents of the packaging (e.g. patient name/description)

- where appropriate, an indication that the device is for single use
- the words 'custom-made'
- any special storage and/or handling conditions,
- any special operating instructions
- any warnings and/or precautions to take
- if appropriate the lot/batch code and year of expiry.

Manufacturers of custom-made devices must draw up a statement for each device. This statement must accompany the device upon issuance of the device to the prescriber or provided directly to the patient. The statement should contain the following information:

- the name or trade name and address of the manufacturer
- data allowing identification of the device in question
- a statement that the device is intended for exclusive use by a particular patient together with the name of the patient
- the name of the registered medical practitioner or other authorised person who made out the prescription and, where applicable, the name of the clinic concerned
- the specific characteristics of the device as specified in the relevant prescription i.e. a documented review of the final product against the prescribed initial requirements
- a statement that the device in question conforms to the essential requirements set out in Schedule I of S.I. 252 of 1994, as amended (equivalent to Annex 1 of the MDD 93/42/EEC) and, where applicable, indicating which essential requirements have not been fully met together with the grounds.

The legislation requires that manufacturers must identify the link between the patient, professional prescriber and manufacturer of the device. This must be defined for every device, together with the particular features of the design as defined by the professional prescriber. For dental custom-made devices, this is often documented in the prescription.

The label and statement requirements above are often documented on the prescription docket generated by the manufacturer. If the dental device is provided directly to the patient by the manufacturer, the manufacturer is responsible for ensuring that they are offered a copy of the statement and providing them with this if requested. Manufacturers should record whether or not the patient chooses to accept a copy of the statement, and if they do not must keep the statement for the lifetime of the appliance.

5.5 Post-market surveillance

Manufacturers must undertake to review and document experience gained in the post-production phase, including the provisions referred to in Schedule 10, and to implement appropriate means to apply any necessary corrective action. This information may be received by the manufacturer in the form of a complaint, a periodic review of the manufacturing process, or other source. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and of the relevant corrective actions:

- any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
- any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to above leading to systematic recall of devices of the same type by the manufacturer.

This means that the laboratory must keep all records of all complaints / device performance issues received and demonstrate that they have applied any corrective actions to address the issues and prevent them from recurring.

Complaints or records of device performance issues must also be assessed to determine if they need to be reported to the HPRA. Issues relating to harm or potential harm caused to patients as a result of the failure of a device must be reported to the HPRA as vigilance incidents. Refer to the '*Guide to incidents for general medical devices and active implantable medical devices*' available on the 'Publications and Forms' section of www.hpra.ie. Any action taken by the laboratory in relation to their dental devices on the market must also be notified to the HPRA, e.g. a device recall.

The laboratory must have procedures in place in relation to these complaint handling, vigilance and corrective action processes.

5.6 Document retention periods

The information contained in the documentation for a particular device should be kept for a period of at least five years. Implantable device information should be retained for at least fifteen years.

The specific requirements and relevant clauses of the legislation are outlined in Annex 1 of this document. An outline of the requirements of the legislation is given in Figure 1.

6 HPRA MARKET SURVEILLANCE

As the Competent Authority for medical devices in Ireland, the HPRA may conduct market surveillance in relation to products manufactured by Irish-based manufacturers and those placed on the Irish market. This post-market surveillance activity forms part of the review of manufacturers' compliance to the EU directives and related Irish regulations by the HPRA.

Market surveillance can take place by way of a review of manufacturer's technical documentation sent in to the HPRA and/or by audit at the manufacturer's premises. The aim of market surveillance is to ensure that the medical device manufacturer is complying with

the essential requirements and schedules of the medical device legislation and related statutory instruments (the Regulations).

Proactive surveillance audits are carried out depending on what the HPRA deems appropriate e.g. targeted audits in relation to a specific category. A 'for cause' audit is conducted as a result of a market issue or potential issue which requires review in the interest of public health. For proactive surveillance audits, a fee per member of the audit team is payable if there are more than 20 employees working at the audited site. No fee or expenses are charged for proactive surveillance audits of medical device companies with less than 20 employees. In relation to 'for-cause' audits, the audit fee per member of the audit team along with expenses such as costs of travel and accommodation is payable.

For additional information in relation to HPRA medical device audits please refer to the HPRA 'Guide for medical device manufacturers on auditing by the Health Products Regulatory Authority to the medical device regulations' and the HPRA 'Guide to fees for human products'.

7 HPRA CONTACT DETAILS

The HPRA encourages communication with the medical device sector. Communication can be made by telephone, fax, e-mail or by post to the address below.

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353 (01) 6764971
Fax: +353 (01) 6767836
E-mail: devices@hpra.ie

ANNEX 1 APPLICABLE LEGISLATION AND REQUIREMENTS

REGULATION IN S.I. 252 OF 1994 AS AMENDED	REQUIREMENT
Article 5 (7)	Requires compliance of a custom-made dental device with the Essential Requirements unless there are reasonable grounds for not complying.
Article 6 (2)	Provides that manufacturers of custom-made devices do not have to place the CE mark on such devices.
Article 14 (1)	Requires manufacturers of custom-made medical devices in the State who place a device onto the market in their own name to inform the HPRA of their registered address, to supply the HPRA with a description of the device which is sufficient to identify it.
Article 14 (3)	Requires persons in the State who have been designated by manufacturers of custom-made medical devices who do not have a registered place of business in the European Union to inform the HPRA of: his/her registered place of business; the type of device; and provide such evidence that he is the authorised representative of the manufacturer. Refer to the *Guide for Custom-Made Medical Device Manufacturers on Compliance with European Communities (Medical Device) Regulations, 1994*, as amended, for more information.
Article 15 (1) (a)	Requires manufacturers of custom-made medical devices to follow the procedure set out in Schedule 8 of the Regulations before such devices are placed on the market.
Article 15 (1) (b)	Requires manufacturers of custom-made medical devices to take all necessary measures to ensure that the manufacturing process for each device conforms to the documentation referred to in Section 3.1 of Schedule 8.
Article 15 (2)	The Minister for Health may require manufacturers of custom-made medical devices to submit a list of custom-made devices which have been put into service in the State.
Article14	Manufacturers of custom-made dental devices in the State, or persons in the State designated by such manufacturers who do not have a registered place of business in the European Union, must register with the Health Products Regulatory Authority i.e. as authorised representatives.
Schedule 1 section 5 section 7	Requires the manufacturer of a custom-made device to consider, with reference to the Essential Requirements: the handling and packaging of the devices the choice of materials (e.g. with regard to toxicity, where there is patient

REGULATION IN S.I. 252 OF 1994 AS AMENDED	REQUIREMENT
	contact, CE marked materials should be used or the manufacturer must guarantee the suitability of the materials by other means)
section 8	cleanliness and cross-infection controls
section 13	information to be supplied by the manufacturer. The minimum requirements regarding the labelling of a custom-made device should include: the name or trade name and address of the manufacturer. For devices imported into the European Union the name and address of an Authorised Representative based in the European Union are required in addition to the name and address of the manufacturer the details strictly necessary for the professional to identify the device and the contents of the packaging; (e.g. patient name/description) the words 'custom-made' any special storage and/or handling conditions any warnings and/or precautions to take
Schedule 1, 6a	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Schedule 10.
Schedule 8, section 2.1	If the Essential Requirements are not fully met, the areas of non-compliance must be stated together with the grounds.
Schedule 8, sections 1, 2, 3 and 4	Before a custom-made dental device is placed on the market, the manufacturer or its designated representative in the European Union must draw up a statement that the device conforms to the relevant requirements of the Regulations. Manufacturers of custom-made devices must draw up a statement for each device which contains the following information: data allowing identification of the device in question, a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient, the name of the registered medical practitioner or other authorised person who made out the prescription and, where applicable, the name of the clinic concerned, the particular features of the device as specified in the relevant medical prescription, a statement that the device in question conforms to the essential requirements set out in Schedule I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds. A copy of this statement should be provided to the prescriber along with the finished device.
Schedule 8, sections 3 and 3.1	Under these sections, manufacturers of custom-made devices must keep available for the Competent Authorities i.e. the HPRA, documentation

REGULATION IN S.I. 252 OF 1994 AS AMENDED	REQUIREMENT
	allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of the Regulations. The manufacturer must also take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph i.e. a documented review of the dentist's requirements to ensure that adequate information has been supplied by the dentist and to demonstrate an understanding of the manufacturing requirements for the design, defined processing parameters together with the choice of materials used, use of CE-marked materials where there is patient contact or the manufacturer must guarantee the suitability of materials by any other means, manufacturing under controlled conditions e.g. following defined/documented processes and some method of demonstrating that they are being followed (e.g. records/work instructions which can be used to show traceability), using suitably qualified personnel, where appropriate, undertaking calibration and maintenance of equipment, considerations of cleanliness and infection control defined handling activities and packaging and a documented review of the final product against the prescribed initial requirements before it is placed on the market.
Schedule 8, section 4	This section states that the information contained in the declarations concerned by this Schedule should be kept for a period of at least five years. The records to be kept will include the statement required under Schedule 8 Sections 1, 2 and 2.1, the review of the prescribed requirements and final product, identification of the materials used, production process monitoring, maintenance and calibration. For all devices, the manufacturer is required to conduct conformity assessment according to the essential requirements before placing the device on the market. Data indicating compliance must be available to the Competent Authority i.e. HPRA by way of a technical file. The Health Products Regulatory Authority encourages manufacturers and users to report any incidents with custom-made dental devices to the HPRA using our Initial Vigilance Report Form and User Report Form, which are available on request or via our website www.hpra.ie.
Schedule 5, section 3	For custom-made devices, the manufacturer must undertake to review and document experience gained in the post-production phase,

REGULATION IN S.I. 252 OF 1994 AS AMENDED	REQUIREMENT
	including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and the relevant corrective actions: any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

FIGURE 1 REQUIREMENTS OF S.I. NO. 252 OF 1994