Safeguarding public health

MHRA

COMPETENT AUTHORITY (UK)

10 EC MEDICAL DEVICES DIRECTIVES

GUIDANCE NOTES FOR MANUFACTURERS OF DENTAL APPLIANCES

(CUSTOM MADE DEVICES)
Updated March 2008

Medicines and Healthcare products Regulatory Agency

CONTENTS PAGE

In line with the requirements of the Hampton Report on Reducing Administrative Burdens - Effective Inspections and Enforcement, MHRA keeps its guidance documents under constant review. If you have any feedback, particularly on the presentation, accessibility or clarity of any of our guidance notes or bulletins please inform the contact person indicated at the end of the individual document.

INTRODUCTION

The Medical Devices Directive (Directive 93/42/EEC) was adopted by the European Council of Ministers on 14 June 1993. See the Official Journal of the European Communities, ref. L169, dated 12 July 1993.

The Medical Devices Directive, regulating the safety and marketing of all medical devices whether used in the public or private sector, required member states of the European Community to put into effect provisions to implement the Directive as from 1 January 1995. The UK Regulations covering these provisions are the Medical Devices Regulations 2002 (SI 2002 No 618).

The purpose of this document is to provide a set of guidelines to enable devices manufactured in a dental laboratory to meet the requirements of the Medical Devices Directive. This document was drawn up in collaboration with the Dental Laboratories Association. A summary of the requirements which are relevant to the activities of dental laboratories is attached as Appendix 1. Compliance is not expected to have significant cost consequences.

Dental appliances, specifically made for a particular patient, are defined as custom-made devices and the requirements of Annex VIII of the Medical Devices Directive will apply to those who wish to manufacture these products.

Where there is reference in the text to medical practitioner and written prescription, as quoted from the Medical Devices Directive, these terms also refer to dental practitioner and dental prescription respectively.

These guidelines must not be regarded as an authoritative statement of the law. Information may be sought from the Competent Authority, which in the UK will be the Medicines & Healthcare products Regulatory Agency of the Department of Health. Manufacturers are advised to consult their own legal advisers if they are in need of legal interpretation of the Directive or the implementing regulations.

DEFINITION OF DENTAL APPLIANCES AS CUSTOM- MADE DEVICES

Article 1 of the Medical Devices Directive gives definitions and the scope for its application. Paragraph 2(a) gives the definition of a 'medical device'. Dental appliances fall within this definition and will be required to meet the requirements of the above Directive.

The following are definitions from the Directive:

- ***'MANUFACTURER'*** *means 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 this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, 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 subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.

However in the manufacturing cycle of a dental appliance, it is the dentist who undertakes the design of the product and the dental laboratory manufactures it to a predefined specification. Under the definitions of the Medical Devices Directive:

- *'**CUSTOM-MADE DEVICE'** means 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, whether NHS, private or independent.*

  The above mentioned prescription may also be made out by any other person authorised by virtue of his professional qualifications to do so.

  Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom-made devices.

If manufacturing is carried out in accordance with a duly qualified medical practitioner's written prescription for the sole use of a particular patient, then the product is considered to be a 'custom-made device'. The requirements are not intended to interfere in any way with the professional and clinical responsibilities of the dentists. The professional activities (eg preparation, impression taking, prescribing, final fitting and any adaptation) carried out by dentists in the supply and fit of dental appliances are outside the scope of the Medical Devices Directive and as such dentists are not considered as manufacturers. Thus a dental appliance is considered to be a custom-made device and the manufacturer of such a device must meet the particular requirements of the Medical Devices Directive which relate to custom-made devices. These are discussed below.

DISCUSSION OF THE ARTICLES OF THE MEDICAL DEVICES DIRECTIVE WITH PARTICULAR REFERENCE TO CUSTOM-MADE DEVICES

In the production of custom-made devices attention must be paid to the regulations which refer to *all* the requirements of the Medical Devices Directive as defined in Articles 1 to 21

(eg. Article 20 requires that all parties are bound to observe confidentiality with regard to all information obtained in the application of the Directive). The manufacturer must identify those which are applicable. Article 3 references the essential requirements (defined in Annex I) which the manufacturer must take into consideration.

The following articles refer directly to the production of a custom-made device.

- ***Article 4.*** *Free movement, devices intended for special purposes (paragraph 2 second indent). Member States shall not create any obstacle to:*

  custom-made devices being placed on the market and put into service if they meet the conditions laid down in Article 11 in combination with Annex VIII; Class II(a), II(b) and III devices shall be accompanied by the statement referred to in Annex VIII.

  These devices shall not bear the CE marking.

- ***Article 10****. Information on incidents occurring following placing of devices on the market. There is no statutory requirement for manufacturers to report serious incidents to the Competent Authority. However the voluntary user reporting system will continue to apply. The UK Department of Health will investigate all reported incidents with custom-made devices. This article will not affect complaints procedures under the GDS and the Dental Practice Board.*

- ***Article 11.*** *Conformity assessment procedures. (paragraph 6). To comply with the Medical Devices Directive a producer of custom-made devices must follow the procedures referred to in Annex VIII.*

- ***Article 14.*** *Registration of persons responsible for placing devices on the market. A manufacturer of custom-made devices or his authorised representative must register with the Competent Authority of the Member State in which he has his registered business with a description of the devices concerned and the business address. The UK Competent Authority will issue a uniform registration application form.*

- ***Article 14(2)*** *also requires that manufacturers outside of the Community must designate a responsible person within a member state who must themselves register with the Competent Authority and provide a description of the devices concerned.*

  If the custom-made device in question would have been classified as either a Class IIa, Class II(b) or Class III device, within the definition of a medical device, contained in Article 1(2)(a) of the Directive, then that device must be accompanied by the statement referred to in Annex VIII. Custom-made devices must be identified as "custom-made". (Annex I 13.2g).

To summarise:

- *Custom-made devices shall not carry a CE marking. (Article 4 paragraph 2).*
- *A manufacturer of a custom-made device must register with the Competent Authority of the member state in which he has his business (Article 14).*
- *Before a device is placed on the market there is a statement, drawn up by the manufacturer or his authorised representative established in the Community, that the device conforms to the relevant requirements of the Directive. (Annex VIII paragraphs 2.1 and 3).*

ANNEX VIII STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

Annex VIII of the Medical Devices Directive defines the requirements that must be met by the manufacturer of a custom-made device. With reference to Annex VIII paragraphs 1, 2 and 2.1; the manufacturer of a custom-made device 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 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 Annex I and, where applicable, indicating which essential requirements have not been full met, together with the grounds.*

If the custom-made device would have been classified as Class IIa, IIb or III under the Directive then a copy of the statement must accompany the device back to the prescriber (see Article 4, Paragraph 2, Second Indent).

The Medical Devices Directive requires that the manufacturer must identify the link between the patient, the dentist and the dental laboratory. This must be defined for every device, together with the particular features of the design as defined by the dentist.

The manufacturer of a custom-made device must ensure that the device conforms to the relevant essential requirements of the Directive as defined in Annex I and declare that the device is in compliance with them. Any requirements which have not been fully met must be stated together with the grounds.

WITH REFERENCE TO ANNEX VIII PARAGRAPHS 3 AND 3.1;

3. *The manufacturer must also undertake to keep available for the competent national authorities:*

3.1 *for custom-made devices, documentation 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 this Directive.*

The manufacturer must 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.

In order to fulfil the above requirements, it is considered that the following activities would need to be undertaken:

- *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 ie. Choice of materials, processing parameters.*

- *Manufacturing under controlled conditions eg following defined/documented processes, and have some method of demonstrating they are being followed [eg records]; using suitably qualified personnel; where appropriate undertaking calibration and maintenance of equipment; considerations of cleanliness and infection control; defined handling activities and packaging.*

- *A documented review of the final product against the dentist's initial requirements, before it is placed on the market.*

PARAGRAPH 4 OF ANNEX VIII REQUIRES:

- *The information contained in the declarations covered by this Annex should be kept for a period of time of at least five years.*

It is unlikely that the control systems will be routinely audited by the Competent Authority (or other regulatory body), but it will have the right to do so if it is deemed necessary.

THE ESSENTIAL REQUIREMENTS OF THE MEDICAL DEVICES DIRECTIVE AND CUSTOM-MADE DEVICES

Annex VIII makes reference in general terms to the requirement for manufacturing custom-made devices under controlled conditions. The essential requirements (Annex I) also specify design and manufacturing controls. The essential requirements must be reviewed by the manufacturer of a custom-made device and the relevant ones complied with. If the essential requirements are not fully met, the areas of non-compliance must be stated together with the grounds (Annex VIII paragraph 2.1).

It is considered that if the laboratory has manufactured the device to the prescribed requirements of the dentist it should, if the dentist has supplied the correct information, be fit for its intended purpose and not harm the clinical condition of the patient.

In addition to the general requirements of Annex VIII, the manufacturer of a custom-made dental appliance must also consider, with reference to the essential requirements:

- *handling and packaging of the devices, (Annex I.I.5),*
- *the choice of materials (eg with regard to toxicity/radiation emission, where there is patient contact CE marked materials should be used or the manufacturer must guarantee the suitability of the materials by other means.), (Annex I.II 7.1),*
- *cleanliness and cross-infection controls, (Annex I.II 8),*
- *information to be supplied by the manufacturer, (Annex I.II 13). Specific requirements for instructions and labelling are defined.*

The minimum requirements regarding the labelling of a custom-made dental appliance should include: (Annex I.II 13.3),

(a) 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 Union;

(b) The details strictly necessary for the dentist to identify the device and the contents of the packaging; (eg patient name/description);

(g) The words 'custom-made';

(i) Any special storage and/or handling conditions;

(k) Any warnings and/or precautions to take.

However it is for the manufacturer of the device to review all the requirements against his procedures. The manufacturer must also review the requirements regarding the information that is to be supplied with the device and determine what is appropriate for his products.

CONTACT POINT

FURTHER INFORMATION ABOUT THE MEDICAL DEVICES DIRECTIVE CAN BE OBTAINED FROM:-

MHRA
Market Towers
1 Nine Elms Lane
London
SW8 5NQ.

Tel: 020 7084 3300
Fax: 020 7084 3112

Email: ERA@mhra.gsi.gov.uk
Internet: http://www.mhra.gov.uk

APPENDIX 1

SUMMARY OF THE GUIDANCE NOTES REGARDING THE ACTIVITIES TO BE UNDERTAKEN BY DENTAL LABORATORIES TO MEET THE REQUIREMENTS OF THE MEDICAL DEVICES DIRECTIVE

STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

The manufacturer of a custom-made device must draw up a statement for each device which contains the information shown overleaf. (For devices that would have been Class IIa (if not defined as 'custom-made' eg, fixed prostheses) a copy of this statement must accompany the device).

MANUFACTURING UNDER CONTROLLED CONDITIONS

The manufacturer must be able to demonstrate that work is being carried out under controlled conditions. This will include:

- *A documented review of the dentist's requirements (to demonstrate an understanding of the manufacturing requirements for the design). The processing parameters must be defined together with the choice of materials used including an indication of the quality and quantity of any precious metals or non-precious metal alloys forming part of the completed device. CE marked materials should be used where there is patient contact or the manufacturer must guarantee the suitability of materials by other means.*

- *Defined manufacturing processes (eg work instructions).*

- *Suitably qualified personnel.*

- *Where appropriate, calibration and maintenance of equipment (eg thickness gauges).*

- *Cleanliness and cross-infection controls.*

- *Defined handling activities and packaging requirements.*

- *A documented review of the final product, against the dentist's initial requirements before it is supplied.*

- *Records should be maintained for a period of time of at least 5 years to demonstrate manufacturing control. These will include: the statement as defined in (1.) above, the review of the dentist's requirements and final product, identification of the*

materials used, production process monitoring and maintenance and calibration and whether supplied for a NHS, private or independent patient.

THE MINIMUM REQUIREMENTS REGARDING THE LABELLING OF A DENTAL APPLIANCE SHOULD INCLUDE:

The name or trade name and address of the manufacturer(s).

- *The details strictly necessary for the user to identify the device and the content s of the packaging.*
- *The words "custom-made".*
- *Any special storage and/or handling conditions.*
- *Any warnings and/or precaution's to take.*

However it is for the manufacturer of the device to review all the information and labelling requirements against his practices.

REGISTRATION OF PERSONS RESPONSIBLE FOR PLACING DEVICES ON THE MARKET

A manufacturer of custom-made devices must register with the Competent Authority of the Member State in which he has his registered business with a description of the devices concerned and the business address(es).

COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

ANNEX VIII (PARAGRAPH 2.1)

For every device there must be a statement 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 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 Annex I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds.*