Orthodontic Products Update

The Medical Devices Directive: is your Laboratory Prepared?

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The Medical Devices Directive (93/42/EEC), which regulates the safety and marketing of all medical devices, is now fully effective. Despite a transition period which started over 3 years ago, there is still a great deal of ignorance within dentistry as to who this legislation concerns and how to comply.

Since June 13th, 1998, all manufacturers of medical devices will have had to comply with the requirements of the Medical Devices Directive. This legislation aims to provide uniformity of regulations throughout the European Union by stipulating various essential requirements to be met by all manufacturers before marketing their products.

Meeting these requirements ensures that medical devices supplied on the European market achieve their intended and declared performance in terms of quality and safety requirements, and therefore do not jeopardize the health and safety of patients, users or other individuals.

This directive encompasses a vast array of medical equipment, instrumentation and appliances, many of which will be mass produced whilst others, including dental appliances will be custom-made.

The Directive offers the following definitions:

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.
Custom-made 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.

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

The conclusion, therefore, is that the dental laboratory is the manufacturer producing custom made devices to the dentist's predefined specification. Furthermore, the professional clinical activities carried out by dentists in the supply and fit of dental appliances such as preparation, impression taking, prescribing, final fitting, and any adaptation are stated to be outside the scope of the MDD and, as such, dentists are not considered as manufacturers.

For manufacturers of custom-made devices, there are five essential requirements specified in the Directive.

First Requirement

A statement is required from the manufacturer containing 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 authorized person who made out the prescription and the name of the clinic concerned.
- The particular features of the device as specified in the relevant prescription.
- A statement that the device in question conforms to the essential requirements set out in Annex 1 of the directive and where applicable, indicating which essential requirements have not been fully met along with the grounds.

Second Requirement

The manufacturer must undertake to keep available for the Medical Devices Agency the following:

- For custom made devices, documentation allowing an understanding of the design, manufacture and performance of the products, including the expected performances, so as to allow assessment of conformity with the requirements of this Directive. It may not be necessary to have a full scale quality system to meet this requirement. Small laboratories may be able to demonstrate conformity by ensuring that its procedures are fully supported by appropriate documentation.
- The manufacturer must take all the measures necessary to ensure that the manufacturing processes produces products which are manufactured in accordance with the documentation mentioned in the paragraph above.

Third Requirement

Information contained within the declaration (in effect the first and second requirement) should be kept for at least 5 years.

Fourth Requirement

The finished dental appliance must be suitably labelled to meet the requirements of the directive. As a minimum the following data will be required:

- The name and address of the manufacturer
- The details strictly necessary for the user to identify the device and the contents of the packaging.
- The words 'custom made device'.
- Any special storage and/or handling conditions.
- Any warnings and or precautions to take.

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Fifth Requirement

A manufacturer of custom made devices must register the business with the Medical Devices Agency with a description of the devices concerned and the business address.

The Directive applies equally to all manufacturers irrespective of their size. The more adventurous may attempt this unaided,whilst for those who find the task too daunting to undertake alone, professional help may be imperative. Either way, it is the second requirement which involves most effort. The first and fourth can be satisfied with the provision of a standard label to be provided with each completed item of work. The fifth is to register with the MDA and the third directs the laboratory to keep all records connected with the manufacturing process and the MDD system for at least 5 years, which will include copies of all the prescription forms for the work they undertake.

Meeting the second requirement essentially means implementing a system to document laboratory procedures and maintain records. In addition to details already mentioned, this should specifically include information about the following:

- Handling and packaging of the devices.
- The choice of materials which will contact the patient, showing evidence of suitability for use.
- Cleanliness and cross-infection controls.
- Prescription review.
- Defined manufacturing processes: work instructions.
- Suitably qualified personnel.
- Essential maintenance and calibration of equipment as appropriate.
- Final inspection of the product against the dentists initial prescription, before dispatch.

In most circumstances, medical devices put into service must be CE-marked to show that the device meets the relevant essential requirements of the directive. Custom-made devices are a notable exception to this; hence, dental appliances do not need to be CE-marked after manufacture.

Once all of the requirements are being met, the laboratory must register with the Medical Devices Agency. This is free of charge and is a simple form to complete. Having undertaken so much, some laboratory owners may be disgruntled to find that they do not receive any kind of formal certification to demonstrate to clients that they are registered, although they do receive a letter from the MDA confirming registration.

It is important to remember that the Directive is statutory and, rather like Health and safety legislation, manufacturers ignore it at their own peril. The MDA, as the UK competent Authority, has the responsibility of policing this. Laboratories that have registered with the UK Competent Authority can be selected at random for compliance inspection and any instances of non registration drawn to their attention after 13 June will be investigated by MDA's Compliance Unit. If dentists feel uneasy that they could be using an illegal laboratory they can ask them for proof of their registration. Due to their statutory obligation to maintain confidentiality, MDA cannot publish a list of registered laboratories, but any laboratory that has nothing to hide should provide a copy of the confirmation letter they get from MDA on request. If this is not forthcoming, then report them to the MDA and consider changing your laboratory. MDA has powers under the Consumer Protection Act 1987 to prosecute, fine, and imprison laboratory owners who do not meet the requirements of the Regulations and to remove their products from the market.

Reference Source

Medical Devices Agency guidance notes No 10 for manufacturers of dental appliances.

Further information can be obtained from: Richard Gutowski, Medical Devices Agency, Room 105, Hannibal House, Elephant & Castle, London SE1 6TQ, UK.