Pav Dental

Medical Devices Regulation Policy

From 26 May 2020, the current Medical Devices Directive (MDD) will change to become the Medical Device Regulations (MDR).

There is now a requirement that the statement of manufacture should be available to each patient for whom a custom-made device has been manufactured.

As defined by UK MDR 2002 5 (1), a custom-made device is:

- manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other person authorised to write such a prescription by virtue of their professional qualification, which gives under their responsibility, specific characteristics as to its design.
- intended for the sole use of a particular patient but does not include a mass-produced product which comprises a medical device and medicinal product forming a single integral product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user.

All manufacturers of custom-made dental appliances are required by the Medical Devices Regulations (MDR) to:

1. Register with the Medicines and Healthcare Products Regulatory Agency (MHRA) and provide your business address and a description of the devices you produce.
2. Meet the requirements of the MDR, which relate to custom-made devices.

At Pav Dental we will ensure that any dental laboratories used by us are registered with the MHRA.

Any custom-made devices will return to the practice with a statement of manufacture. We will make our patients aware that this statement is available.

The statement of manufacture should include the following information:

- the name and address of the manufacturer, and if outside the EU their authorised representative
- data allowing identification of the device in question
- a statement that the device is a custom-made dental appliance and intended for exclusive use by a particular patient, together with the name of the patient
- the name of the practitioner or other authorized person who made out the prescription and, where applicable, the name of the practice concerned
- the specific characteristics of the product as indicated by the prescription

- a statement that the device in question conforms to the essential requirements of the Medical Devices Directive

Service and Repair

Medical devices may require routine user maintenance, planned preventive maintenance (e.g., by trained technicians) and ad-hoc maintenance if faults occur. Many require periodic performance checks which may require specialist test equipment. Evaluate the user maintenance and planned maintenance recommendations for the device (including frequency and type). Evaluate the ease of breakdown maintenance, particularly in relation to how this will be provided, and the response time provided by the supplier for breakdown maintenance. Ensure that all medical devices can be stored, maintained, and serviced in line with the manufacturer's instructions for use. Consider all the costs associated with these before buying.

Document Control

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The latest approved version of this document supersedes all other versions, upon receipt of the latest approved version all other versions should be destroyed, unless specifically stated that previous version(s) are to remain extant. If in any doubt, please contact the document Author.

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