

STANDARDS ON COMMISSIONING AND MANUFACTURING DENTAL APPLIANCES FAQs

What dental devices are subject to the Medical Devices Directive 93/42/EC (MDD) regulations?

All 'custom-made devices' are subject to the MDD regulations, these are any device specifically made in accordance with a duly qualified medical or dental practitioner's written prescription with specific design characteristics and intended for the sole use of a particular patient, whether NHS, private or independent.

Examples include:

Appliances mainly constructed out side of the mouth on a model, including - man-made temporary crowns, TMJ splints such as Michigan and Tanner, Dentures/Crowns/Bridges, removable orthodontic appliances, etc.

Cad-Cam - although the dentist takes a digital image and it is fitted whilst the patient is there, the machine makes the filling inlay/ onlay/ crown/bridge etc. extra-orally and it is intended to last long-term.

A denture constructed mainly outside of the mouth for someone who has lost a tooth, including if only intended to last a week while a better alternative is made.

What dental devices are not subject to the MDD regulations?

Normal dentistry that uses dental materials intra-orally.

Examples include:

Fillings, temporary fillings, temporary crowns, splinting teeth, etc

A dental intra-oral filling, even if so large it's an Onlay, made intraorally

A temporary Bridge made from acrylic intra-orally while a better alternative was being constructed

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.

Etched orthodontics

Registrants where the manufacture of dental appliances (for example fixed bridges, crowns, etc.) occurred mainly outside of the mouth

We manufacture 'custom-made' Dentures, Crowns and Bridges etc. in the dental practice, do we need to register with the Medicines and Healthcare products Regulatory Agency (MHRA)?

Yes. The MDD requires that manufactures of any dental device classed as a 'custom-made device' must register with the MHRA, providing them with a description of the devices concerned and the business address.

A registration form can be downloaded from the MHRA website:
www.mhra.gov.uk

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I am constructing a removable orthodontic appliance in a dental practice, what do I need to do?

Removable orthodontic appliances made for an individual patient are a 'custom-made' device so firstly, you need to ensure that the practice is registered with the MHRA. You also need to ensure that you fully comply with the requirements of the MDD as a manufacturer of a custom-made device - this includes providing a statement of manufacture detailing all of the relevant pieces of information.

Registrants providing patients with a dental appliance

As the prescriber of a 'custom-made' device, do I need to comply with the MDD regulations?

Yes. As a GDC registrant you are responsible for finding out about laws and regulations which affect your work, premises, equipment and business, and following them. Also, Ann Keen (Parliamentary Under-Secretary of the Department of Health at the time) has stated that the additional requirements of the MDD - to ensure that the patient is made aware that they can request the statement of manufacture and to ensure that it is made available to the patient if it is requested - are punishable as criminal offences if not complied with.

How does the MDD affect me as the provider of a dental appliance directly to a patient?

As the professional registrant providing the patient with a dental appliance you are responsible for ensuring that they are offered a copy of the statement and providing them with this if they request it. You should record whether or not they choose to accept a copy of the statement, and if they do not you will need to keep the statement for the lifetime of the appliance.

Registrants who arrange for dental appliances to be made in the UK

Who can make a dental appliance in the UK?

Any GDC registrant that is suitably trained and competent to do so can construct a dental appliance so long as it is included as one of the skills or abilities that their registrant group should have, or could develop as an additional skill, in the GDC Scope of Practice guidance booklet.

If I am arranging for a dental appliance to be made in the UK, who can I ask to do this?

If you arrange for a dental appliance to be made in the UK you are responsible for issuing the prescription to and receiving the appliance from a GDC registrant capable of making the appliance. If you do not do this you may face a GDC fitness to practice inquiry.

Who does the manufacturer need to be registered with?

All manufacturers of 'custom-made' dental appliances must register with the MHRA, and provide them with a description of the devices concerned and their business address. The list of registrants with the MHRA will be published on their website: www.mhra.gov.uk

Registrants who arrange for dental appliances to be made outside the UK by non-GDC registered dental technicians

What extra responsibilities do I take on if I obtain a dental appliance made outside of the UK by non-GDC registered dental technicians?

If you decide to prescribe or sub-contract the manufacture of a dental appliance outside of the UK and do not use a GDC registrant, you will be held professionally accountable for the safety and quality of the appliance. This will include ensuring that the statement of manufacture, or if outside of the EU the name and address of the manufacturer are disclosed to the prescriber and patient.

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