

STANDARDS ON COMMISSIONING AND MANUFACTURING DENTAL APPLIANCES

Issued by the General Dental Council under Sections 26B and 36M of the Dentists Act 1984

All GDC registrants involved in prescribing, manufacturing and fitting dental appliances have a role to play in protecting patients from harm and in providing a safe and effective standard of care.

All GDC registrants must comply with the GDC standards guidance. With regards to the commissioning and manufacturing of dental appliances the following principle has particular relevance:

‘Find out about laws and regulations which affect your work, premises, equipment and business, and follow them.’
(Principle 5.4, ‘Standards for dental professionals’)

When commissioning and manufacturing dental appliances this includes compliance with the Medical Devices Directive 93/42/EC.

Compliance is also a legal requirement and failure to comply is a criminal offence.

These overriding principles are complemented by the standards of practice below.

Provision of dental appliance manufacturing services

Patients are able to see dental technicians or clinical dental technicians directly for the repair of dentures, and clinical dental technicians are able to see patients directly for the provision of complete dentures to patients with no natural teeth or implants.

In all other circumstances dental technicians or clinical dental technicians advertising the provision of dental appliances should make it clear that patients need to see a dentist before seeing them.

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

If you make a dental appliance, whether you are a dental technician, dentist, or any other registrant, you must understand and comply with your legal responsibilities as “manufacturer” under the Medical Devices Directive 93/42/EC. (Including registration with the Medicines and Healthcare products Regulatory Agency (MHRA).)

This includes providing a statement of manufacture with the following information when dispatching a dental appliance:

- 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;

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- the name of the practitioner or other authorised 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 set out in Annex I of the Medical Devices Directive 93/42/EC and, where applicable, indicating which essential requirements have not been fully met, together with the grounds.

These are legal requirements. The GDC expects you to fulfil these responsibilities and will hold you accountable for doing so.

Registrants who arrange for dental appliances to be made

If you arrange for dental appliances to be made in the UK, you are professionally responsible for issuing the prescription to and receiving the appliance from a UK-registered dental technician. If you prescribe a dental appliance to be made by a person in the UK who is not a registered dental technician you are liable to face a GDC fitness to practise inquiry. Equally, you may face a GDC fitness to practise inquiry if you receive a dental appliance made in the UK by a person who is not a registered dental technician.

Registrants who sub-contract or prescribe dental appliances to be made outside the UK by non-GDC registered dental technicians

When making the decision to either sub-contract the manufacture of a dental appliance, or use a dental laboratory or agent, which sources dental appliances made by non-GDC registered dental technicians outside the UK, your choice not to use a GDC registered dental technician puts a particular responsibility on you.

You will be held professionally accountable for the safety and quality of the appliance. This is because you have chosen not to sub-contract or issue the prescription to a registered dental technician who would otherwise be accountable him or herself. You take on the dental technician's responsibilities for the appliance and the GDC will hold you accountable for your decision.

We expect you to take appropriate steps to discharge the extra responsibilities that come with this decision. These include a responsibility to ensure that the manufacturer or their authorised representative¹ has complied with all relevant obligations in the Medical Devices Directive. Further, if a dental appliance or any part of it has been manufactured outside the EU, the name and address of the manufacturer should be disclosed to the patient.

Registrants providing patients with a dental appliance

The Medical Devices Directive 93/42/EC requires that the statement of manufacture is available to the patient for whom the dental appliance is made. The patient can request this at any time during the lifetime of the appliance.

You should inform patients of the existence of the statement and offer them a copy. You should record whether or not they choose to take a copy of it. If the patient does not choose to take a copy of the statement, you will need to keep the statement for the lifetime of the device in case it is requested at a later date.

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¹ 'Authorised representative': Where a manufacturer who places a device on the market under their own name does not have a registered place of business in a European Union Member State, they shall designate a single authorised representative in the European Union.

Ref. Article 10a EU Directive 90/385/EEC