

# Crowns, bridges and dentures

## Do you know what's going in your mouth?

If you're having what's called a 'dental appliance' fitted as part of your treatment you can find out more about how and where it was made by asking your dentist for a statement of manufacture.

### What is a 'dental appliance?'

Dental appliances include most things made outside of your mouth on a model.

For example:

- Crowns
- Dentures (including temporary ones)
- Bridges
- Removable orthodontic appliances (plates, retainers)

### What is a 'statement of manufacture?'

The person who prescribes your treatment (usually your dentist) must offer you a statement of manufacture with full details of the appliance. The statement is like a certificate or warranty, and proves that your device has been made to legal standards especially for you.

You don't have to take a copy of the statement. It will be kept on file and you can ask for a copy at any time during the lifetime of the appliance.

You won't receive a new statement if your appliance is repaired or refurbished.

### When did this happen and who enforces it?

Changes were made to the Medical Devices Directive - which outlines legal requirements for dental appliances - and came into force in March 2010.

The European Commission updated the directive so that patients are given the option of having more information about where appliances are made. These changes are overseen by the Government's Medicines and Healthcare products Regulatory Agency (MHRA).

### Where does the GDC fit in?

It's the MHRA, not the GDC, who will enforce the directive, but as the regulator we require all professionals to keep up to date with legal requirements.

We take action where our standards and legal requirements are not met.

### Where can I find out more?

If you would like further information about the Medical Devices Directive and how it affects you, visit the MHRA website: [www.mhra.gov.uk](http://www.mhra.gov.uk) or email your questions to them: [ERA@mhra.gsi.gov.uk](mailto:ERA@mhra.gsi.gov.uk)

## What the statement will include



**Your name**



**Confirmation that the device was custom made for you**



**Who prescribed it (and their address)**



**Who it was made by (and their address)**



**A description of the device**



**Confirmation that it meets legal standards**