



Newsletter: April 2010

Dear Client,

I hope you have noticed the patient statement appearing with finished devices.

The GDC issued Guidance on the 23rd March:

Standards updated on commissioning and manufacturing dental appliances

This reaffirms the guidance from MHRA about the change to the Medical Device Directive 93/42EC which I outlined in the last newsletter.

To quickly paraphrase the guidance from the GDC:

- Compliance with this is also a legal requirement and failure to comply is a criminal offence.
- 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
- 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.
- You should inform patients of the existence of the statement and offer them a copy.
- 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.
- 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.

If you have any questions about the statements please contact me.

Thank you to everyone who helped in setting out the statement and for your advice as to the content. If anyone has any other ideas or improvements I should be happy to hear from you.

Kind regards

David Smith – Managing Director



REGISTERED MEMBER