Standard 1.9 of *Standards for the Dental Team* states that:

'You must find out about laws and regulations affecting your work and follow them'.

Changes to medical devices regulations

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

If you commission and manufacture dental appliances you must comply with the Medical Device Regulations (MDR). Compliance with this is a legal requirement and failure to comply is a criminal offence. Further information can be found on the gov.uk website.

What about a 'No deal' Brexit?

As of 3 January 2019, for medical devices, the key arrangements include:

- for a time-limited period, devices that have a CE mark from a notified body based in the UK or an EU country will continue to be recognized by UK law and allowed to be placed on the UK market
- the expansion of the MHRA's registration system to all classes of medical device.

Further information can be found on the gov.uk website.

Registrants who manufacture dental appliances mainly outside of the mouth

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 Device Regulations (MDR). This includes the legal requirement to register with the Medicines and Healthcare products Regulatory Agency (MHRA).

Registrants who arrange for dental appliances to be made

If you prescribe a dental appliance to be made by a person in the UK who is not a registered dental technician, you may put your registration at risk. Equally, you may put your registration at risk 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

If you decide to either sub-contract the manufacture of a dental appliance or use a dental laboratory or agent which sources dental appliances from outside the UK you take on additional responsibilities. These include a responsibility to ensure that the manufacturer or their authorised representative has complied with all relevant obligations in the Medical Device Regulations (MDR).

If you have concerns about a device

If you are concerned about a device you are using, stop using it and report it to the MRHA: https://www.gov.uk/report-problem-medicine-medical-device