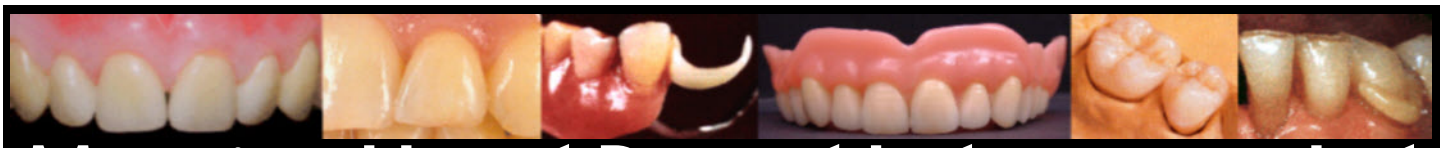

Maurice Hood Dental Laboratory Ltd

LABORATORY NEWS

Medical Devices Directive

Important Changes You Should Know About

From 21 March 2010 there will be a number of important changes to the Medical Devices Directive. The two main changes that will affect all dentists concern the patient statement and post market surveillance & vigilance reporting.

Patient Statement

As you are probably aware you will be obligated to inform every patient that they can request a statement containing the information required by Sections 1 and 2 of Annex VIII. In simple terms this is a copy of the information in relation to the appliance you are fitting. The information must include the name & address of the laboratory, a description of the device and any specific characteristics as indicated in the prescription, the name of the prescriber and, if applicable, the address of the surgery. It must also contain a statement of conformity.

Currently your obligation is only to inform the patient that they can have a copy of the statement - you only have to supply a copy if the patient actually requests it. However, there is a movement to make the supply of the statement to the patient compulsory and it might be best practice to do so now.

As far as all laboratories are concerned we are required to supply you with the statement whether you hand it out or not. To meet our legal obligations, and to ensure you meet yours, we will be issuing a patient statement with every appliance. This will happen automatically on or before 21 March so you need do nothing. Obviously, please feel free to contact us if you have any concerns.

Post Market Surveillance & Vigilance Reporting

The second major change may not directly affect you but it could have serious implications for you in the future. Introduced in the changes is a requirement that all manufacturers of custom made devices, i.e. dental laboratories, must have a documented complaint and recall procedure. There are obvious implications that you could face if there is ever a problem and it transpires that the laboratory you used was not complying with the Medical Devices Directive.

Guaranteed Compliance

Rest assured however, that part of the ISO9001 and DAMAS quality systems is compliance with the Medical Devices Directive. What's more, because we are externally audited every year you can be sure we fully comply with all legal requirements, a guarantee which safeguards both you and your patients.

Quite a few of you have requested a copy of our MDD registration for your records. However, this will no longer guarantee compliance and we would be more than happy to provide you with copies of our ISO9001 and DAMAS certificates. Again, if you would like to discuss this or have any concerns please let us know.

Contact Details
Registered Office:-
Houghton Street
Oldbury
West Midlands
B69 2BB
Tel:-
0121-544 8855
0121-544 8836
Fax:-
0121-544 8835
E-mail:-
info@mauricehood.com
Web:-
www.mauricehood.com