

USING A DAMAS REGISTERED DENTAL LABORATORY



What does this mean for you the dentist?

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the coach house
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ripon, north yorkshire
HG4 1NS

- The laboratory undergoes a yearly site audit.
- The laboratory's Medicines and Healthcare products Regulatory Agency (MHRA) registration is verified.
- The laboratory's dental technicians are checked and verified as registered with the General Dental Council.
- Patient contact materials are verified as CE Marked and fit for their intended purpose.
- The laboratory's equipment maintenance processes are validated as appropriate.
- The laboratory's post market surveillance and vigilance procedures are inspected and verified as complying with the law.
- Purchasing and verification of purchase products to enable traceability of materials is inspected and verified to ensure recalling of devices is possible – should this be necessary.
- Contract review and final inspection of appliances is audited to ensure compliance with the dentist's original prescription.
- Statement and labelling of appliances including issuing the patient statement is verified as complying with the Medical Devices Directive.
- Laboratory sub-contractors are verified as fit for the purpose they are intended for.
- Staff training and competences are checked as verified as undertaken by the laboratory.

DAMAS laboratories undergo yearly audits to gain certification to DAMAS to prove compliance with the Medical Devices Directive (MDD) and the Medical Devices Regulations (MDR) which is a legal requirement within Europe for manufacturers of custom made medical devices.

DAMAS Certified laboratories offer reassurance where other can't because their compliance with the MDD & MDR is independently validated.

For more information on DAMAS visit www.damas.co.uk

MDD and DAMAS registered
Procera network laboratory
3i platinum laboratory
Astra Atlantis laboratory



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