DAMAS EXPLAINED

Dental Appliance Manufacturers Audit Scheme - DAMAS

DAMAS is a voluntary scheme for dental laboratory owners and is an independent check that a dental appliance manufacturer is complying with the MDD and MDR and demonstrates that the manufacturer's registration with the MHRA is correct.

The scheme:

- provides a means of publicly demonstrating a dental appliance manufacturer's capability to supply MDD and MDR conforming appliances;

- ensures that manufactured appliances meet the relevant essential requirements of the MDD and the prescriber's specified requirements;

- allows a dental appliance manufacturer's MDD conformity assessment procedure to be verified by an independent body;

- allows a dental appliance manufacturer's registration claim to be validated.

DAMAS gives dental appliance manufacturers a method of having their MDD registration claim validated by an independent inspection. The DAMAS inspector audits the dental appliance manufacturer's MDD compliance system - and claim to registration with the MHRA - for compliance with the DAMAS Management System Specification. Once the DAMAS Inspector is satisfied that the dental appliance manufacturer is complying with the requirements of the DAMAS specification, then the dental laboratory will be registered as a DAMAS compliant laboratory. The DAMAS certificate may be put on public display, and the manufacturer may use the DAMAS logo on his promotional materials, letterheads, prescriptions, etc.

The benefits of DAMAS to the individual laboratory may be summarised as follows:

DAMAS says that your laboratory complies with the MDD.

DAMAS provides your clients with additional confidence in your capability to supply MDD compliant custom-made dental appliances.

DAMAS limits the risk of litigation for both you and your clients.

DAMAS provides you with a powerful marketing and selling tool, and the opportunity to supply many of the corporate bodies.

DAMAS provides a base for continuous improvement in your business.

The benefits of DAMAS to the industry may be summarised as follows:

DAMAS identifies responsible laboratories.

DAMAS will discourage fraudulent registration claims by dental laboratories.

DAMAS improves and develops the image of the industry.

DAMAS is supported by the Dental Profession, NHS and Dental Protection Bodies.

DAMAS is a process-based system that fully complements recent developments in the ISO 9001 series of standard quality management systems.

The Approach
DAMAS is similar in approach to ISO 9001, but with the ISO 9001 requirements simplified to take into account the practicalities of custom-made dental appliance manufacturing techniques and methods. However, DAMAS does address the main elements of ISO 9001, and registration under DAMAS will give your clients some independent assurance that your laboratory is manufacturing in compliance with the Medical Devices Regulations and Medical Devices Directive.

How does DAMAS work in practice?
Manufacturer must establish and maintain a manufacturing management system. The system must comply with the requirements of the Medical Devices Directive and the requirements of the DAMAS Management System Specification.

DAMAS Management System Specification
The DAMAS Management System Specification is based upon good manufacturing practice and ISO 9001. It specifies management system requirements for use where a dental appliance manufacturer's capability to supply dental appliances in conformance with the Medical Devices Directive and Medical Devices Regulations needs to be demonstrated to others.

The specification specifies requirements for a manufacturing management system that are considered good practice for compliance with the MDD. It provides objective evidence - process controls and records - that the manufacturer is complying with the requirements of the MDD. It allows a third party to assess and verify that a manufacturer's management system complies with the MDD and DAMAS Management System Specification Requirements.

The requirements are based upon the sound quality system principles specified in ISO 9001. However, they have been adapted/simplified to meet the requirements of the MDD/MDR, and to reflect the practical nature of dental appliance manufacture, i.e. reliance on the manufacturing skills of competent dental technicians, rather than on extensive documented procedures/work instructions.

However, a dental appliance manufacturer who maintains an ISO 9001 quality system, will, with very slight additions to his system, readily meet the requirements of the DAMAS Management System Specification.

How compliance with the MDD requirements can be met by the application of the DAMAS Management System Specification.

Clause 4 of the DAMAS Specification contains fifteen sub clauses; 4.1 to 4.15, that specify the requirements that must be satisfied by a custom-made dental appliance manufacturer before he or she can become a DAMAS Registered Dental Appliance Manufacturer.

Sub clauses 4.1 to 4.14 have been designed to allow conformity with Annex I and Annex VIII of the MDD to be demonstrated to others.

Subclause 4.15 Internal audits and management review, are considered good quality assurance practice and are additional to the MDD requirements.

Meeting the DAMAS Management System Specified Requirements

You should now refer to your copy of the DAMAS Management System Specification.

An explanatory note accompanies each specified requirement which is located at the back of the DAMAS Specification.

The explanatory note is aimed at the dental appliance manufacturer, and suggests the methods/approaches that he can take to meet the particular requirements. Note that these are only suggestions, there is no compulsion on the dental appliance manufacturer to adopt the methods/approaches suggested.

The following notes aim to clarify and/or assist in meeting the requirements of the DAMAS Management System Specification. The number on the left, in the text below, is the requirement reference in the DAMAS Management System Specification.

4.1.1 Conformity policy
This may be incorporated within your ISO 9001 quality policy statement in your quality manual, or you may prefer to draw up the statement of conformity based upon the example given in Appendix 1 to the specification.

4.1.2 Management Representative
This should be somebody in management with the authority to make sure everybody complies with the MDD/MDR and DAMAS. It is good practice to make this person responsible for ensuring that the manufacturer carries out internal audits and management reviews correctly.

4.2.1 General
This clause requires you set up a documented manufacturing system and to describe and document the performances and expected performances of the appliances you manufacture. In practical terms, the documented system would be generated by collating into a manual the documentation referred to in clauses 4.3 to 4.15 below.

This clause also requires you to maintain a copy of the Medical Devices Directive and a copy of the Medical Devices Regulations for reference purposes. In addition, it requires you to keep a copy of the registration acknowledgement letter you will have received from the MHRA.

The simplest way to meet this requirement is to establish a set of documented procedures and/or plans and/or flowcharts, on how you manufacture dental appliances. This documentation should be collated into some logical order - usually in a manual.

You should write down the performances and expected performances of dental appliances within the collated documentation.

4.2.3 Registration with Competent Authority

Any documentation and/or correspondence you have had with the MHRA must be maintained in a file and kept until you cease trading.

4.3 Documented Review of the Prescriber's Requirements

This clause requires you to verify that you understand prescriber requirements for the design and manufacture of the dental appliance to be made, and that you record amendments to the prescriber's requirements.

4.4 Patient Contact Materials

This clause requires a record of acceptable suppliers of suitable patient contact materials (oral cavity materials) to be maintained. It also requires the manufacturer to have a documented purchasing procedure in place to ensure that patient contact materials are only purchased from acceptable suppliers, and that these materials are inspected before being released for use.

4.5 Defined Manufacturing Processes

This clause requires the manufacturer to document his manufacturing processes so that they can be clearly understood by others. This may be achieved by the use of flowcharts, work instructions or work plans. The clause also requires manufacturing activities to be carried out by competent persons, and that the materials and equipment they are using to manufacture dental appliances are used in accordance with the supplier's guidance instructions and in accordance with the generally acknowledged state of the art.

4.6 Training

This clause requires the manufacturer to establish and maintain staff training records that show the competencies in manufacturing activities of each staff member.

4.7 Maintenance and Calibration of Equipment

This clause requires the manufacturer to carry out suitable maintenance and calibration activities where appropriate. Where the calibration of equipment is not deemed to be required, then there is no need to carry out calibration activities.

4.8 Cleanliness
This clause requires the manufacturer to carry out periodic cleaning of his manufacturing plant and equipment and to record that it has been done.

4.9 Documented Review of the Final Product
This clause requires the manufacturer to inspect and verify that the finished dental appliance complies with the prescriber's requirements. The specification stipulates the minimum attributes that must be subjected to inspection to ensure that the inspection and verification process is carried out correctly. Retaining a signature that a competent person gave the finished appliance a final inspection is important. You should add the appropriate part of the DAMAS Final Inspection Checklist to your procedure.

4.10 Defined Handling and Packaging Requirements
This clause requires the manufacturer to establish and maintain procedures that will maintain and ensure the integrity of finished appliances after final inspection and during delivery to the prescriber.

4.11 Control of records
This clause requires the manufacturer to establish and maintain records to demonstrate that he is complying with the requirements of the specification, e.g. copies of prescriptions, records of approved materials and suppliers, purchase orders, materials and equipment guidance notes, maintenance logs, staff training records, etc. These records must be kept for five years after they have been first generated.

4.12 Statement
This clause requires the manufacturer to draw up the statement required in Annex VIII of the MDD. If the manufacturer's dental appliances are classified as Class IIA under the MDD classification rules, then a copy of this statement must accompany the finished appliance when it is given to the prescriber. All registered labs should be doing this anyway.

This is best incorporated within your labelling system. Make sure that you have addressed all the requirements for a statement before going ahead with printing new stationery.

4.12.1 Patient Statement
This clause requires the manufacturer to supply a patient statement with the finished appliances so it can be made available to the patient by the healthcare professional who writes the prescription.

There are no strict guidelines on how the patient statement should be presented, however, it is compulsory for the following details to be present:

- Name & Address of Laboratory

- Description of Device
- Names of Prescriber and if applicable address of Clinic
- The Statement of Conformity

The laboratory should decide the most appropriate method which can include for example - a separate patient statement or a triplicate of the lab ticket.

4.13 Labelling

This clause requires the manufacturer to label his finished appliances in accordance with Section 13 of Annex I of the MDD - Information supplied by the manufacturer. Again, all registered labs should be doing this anyway.

Make sure that you have addressed all the requirements for labelling before going ahead with printing new stationery.

4.14 Post Market Surveillance and Vigilance Reporting

This clause requires the manufacturer to maintain a system for handling and resolving complaints and also have a procedure in place should the need arise to recall appliances.

4.15 Internal audits and management review

This clause requires the manufacturer to establish and maintain an internal audit plan to ensure that the management system continues to meet the DAMAS management system requirements. The system must be audited it at least once per year.

Manufacturer reviews should focus on the critical elements of the manufacturing process and the specified requirements of this specification. Required changes and actions, identified through management review, should be promptly implemented. The effectiveness of these changes and actions should be evaluated at the next management review or sooner as appropriate.

Certification and Registration

When you have carried out at least one internal audit of your manufacturing system, and you are satisfied that it complies with the DAMAS management system requirements, then you can apply for your formal DAMAS audit/inspection.

The steps are as follows:

Complete the DAMAS Audit Application Form.

The DAMAS office will arrange a date for the assessment of your system.

An auditor will visit your premises, and assess your system for compliance with the requirements of the DAMAS Management System Specification.

If the auditor feels that you are not complying with one or more of the requirements of the Specification, then they will raise a noncompliance report and ask you to countersign it that you agree with the identified non-compliances. You will then be asked for a response to the non-compliances, i.e. a written response about what you

are going to do to correct the non-compliances.

Once the auditor has assessed that your laboratory has met the DAMAS requirements, the DAMAS office will then issue you with a DAMAS compliance certificate, and place you on the DAMAS Register.

Once you have passed the first audit you will be assessed once per year. If you do not maintain your system correctly, the DAMAS Office will withdraw your certification and registration.

DAMAS Logo

You can use the DAMAS Logo for promotional and advertising purposes while you maintain a valid certificate of DAMAS compliance.

SUMMARY

DAMAS provides a system of good manufacturing practice that will enable any custom-made dental appliance manufacturer to set up a manufacturing system in conformity with the requirements of the Medical Devices Directive.

To conform with the requirements of the DAMAS specification, a system of operational procedures needs to be established and maintained. The procedures should generate objective evidence - records - that the procedures are working effectively.

The system will then provide a manufacturer’s clients with independent verification that the manufacturer is complying with the requirements of the Medical Devices Directive. That is, clients will have enhanced confidence in the manufacturer’s capability to supply satisfactory and MDD compliant custom-made dental appliances.