DENTAL LABORATORIES ASSOCIATION LTD

DENTAL APPLIANCE MANUFACTURERS AUDIT SCHEME (DAMAS)

MANAGEMENT SYSTEM SPECIFICATION

DAMAS
Dental Appliance Manufacturers Audit Scheme

Contents **Page**

Amendments issued since publication

Amendment No.	Date	Text affected
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

0 Introduction

The Dental Laboratories Association Ltd (DLA) has produced this specification. By complying with the requirements of this specification, a dental appliance manufacturer can demonstrate they have the capability to manufacture custom-made dental appliances in compliance with the Medical Devices Directive (MDD), the Medical Devices Regulations (MDR) and the DAMAS Management System Specification.

This specification may be used by custom-made dental appliance manufacturers - whose manufacturing operations are not subject to United Kingdom Regulations - to demonstrate compliance with the Country and/or State Regulations that apply to their own particular manufacturing operations. Refer to the Scope below.
This specification aims to provide sources of objective evidence that will allow a third party to assess a custom-made dental appliance manufacturer's conformity with the specification requirements.

NOTE 1 The Medical Devices Regulations does not require third party audit for compliance and registration purposes. It is each dental appliance manufacturers responsibility as to how they meet the requirements.

NOTE 2 The requirements specified in this Issue 7 of the DAMAS Management System Specification have been updated to reflect the amendments required within the Medical Devices (Amendment) Regulations 2008 SI No 2936 and Directive 2007/47/EC of the European Parliament and of the Council. It is the responsibility of each dental appliance manufacturer to ensure they meet these amended requirements which apply from 21st March 2010.

NOTE 3 Changes to Issue 6 have been made:

- to updated references to the MDD/MDR as detailed in Annex A.
- to include a clause relating to the patient statement 4.12.1.
- to include a clause for the requirement of 'Post Market Surveillance and Vigilance reporting' and 'Appliance Recall' 4.14 & 4.14.2.

1 Scope

This Specification specifies management system requirements for use, where a dental appliance manufacturer's capability to supply custom-made dental appliances, in compliance with the Medical Devices Directive and/or Medical Device Regulations, and/or other Regulations needs to be demonstrated to others.

The requirements specified are aimed at achieving prescriber satisfaction by preventing nonconformity at all stages of dental appliance manufacture.

In this specification, the terms "appropriate", "if appropriate" and "where appropriate" are used. These terms aim to facilitate the use of this specification by dental appliance manufacturers whose manufacturing operations are not subject to United Kingdom Regulations. When a requirement is qualified by any of these terms, it is deemed to be "appropriate" unless the dental appliance manufacturer can document a justification otherwise. A requirement is considered "appropriate" if it is necessary in order for:

- the product to meet specified requirements, and/or
- the dental appliance manufacturer to carry out corrective action, and/or
- the dental appliance manufacturer to conform with the requirements of an audit scheme that uses this specification to demonstrate conformance with the scheme requirements.

2 Normative references

The references in Annex A are indispensable for the application of this specification. The dental appliance manufacturer shall ensure that the appropriate and latest edition of the references (including any amendments) is used in the application of this specification.

3 Terms and definitions

For the purposes of this specification the following terms and definitions apply:

Manufacturer	As defined in the Medical Devices Directive
Custom-made medical device	As defined in the Medical Devices Directive
Supply chain	Supplier/Subcontractor → Dental Appliance Manufacturer → Customer
Supplier	Party supplying materials to the Dental Appliance Manufacturer.
Subcontractor	Party supplying part constructed or fully constructed dental appliances to the Dental Appliance Manufacturer.
Dental appliance manufacturer	Party responsible for the manufacture of the custom-made dental appliances to which this specification applies.
Customer	Party responsible for prescribing and specifying the design characteristics of a custom-made dental appliance. Normally a duly qualified medical practitioner or other person authorized by virtue of their professional qualifications. For the purposes of this specification, the term "customer" is synonymous with the term "prescriber".
Customer complaint	Written, electronic or oral communication that alleges deficiencies related to the quality, durability, reliability, safety or performance of a medical device that has been placed on the market.
Competence	Demonstrated ability to apply knowledge and skills.
Nonconformity	Non-fulfilment of a requirement
Label	Written, printed or graphic matter - affixed to a medical device or any of its containers or wrappers, or, - accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.
Prescription	Information allowing an understanding of the prescriber's requirements for a custom-made medical device.
Third party certification body	An independent body accredited by a competent body to carry out assessments of quality systems.

4 Management system requirements

4.1 Management responsibility

4.1.1 Conformity policy

The dental appliance manufacturer shall define and document their commitment to conformance with the Medical Devices Directive (MDD), Medical Devices Regulations (MDR) and Dental Appliance Manufacturers Audit Scheme (DAMAS). Where appropriate, the commitment to conformance with the MDD and MDR shall be replaced by a commitment to conformance with the Regulations that apply to the dental appliance manufacturer's activities. See Annex A.

This commitment to conformance document shall be a public quality policy and objectives statement or a public statement of conformity. See Annex D.

4.1.2 Management representative

The dental appliance manufacturer shall appoint a management representative who shall have responsibility for ensuring that the requirements of this specification are implemented and maintained.

4.2 Management system

4.2.1 General

The dental appliance manufacturer shall establish, document and maintain a dental appliance manufacturing system as a means of ensuring dental appliances are manufactured in conformity with the appropriate Regulations.

The system shall be suitably described and documented so as to allow an understanding of the design, manufacture and performance of the dental appliances, including the expected performances, and to allow assessment of conformity with the requirements of the appropriate Regulations and the requirements of this DAMAS Management System Specification.

The dental appliance manufacturer shall describe and document the performance and expected performances of each type of dental appliance manufactured.

4.2.2 Legal and system documentation

The dental appliance manufacturer shall retain copies of the DAMAS Management System Specification and appropriate Regulations. See Annex A.

4.2.3 Registration with the competent authority

The dental appliance manufacturer shall be registered with the relevant European Union Competent Authority or with the appropriate registrar. Customers and third party assessment bodies shall be allowed access to the documentation that verifies this registration.

4.3 Documented review of the prescriber's requirements

The dental appliance manufacturer shall ensure that prescriber requirements are adequately defined and documented so that the dental appliance manufacturer can demonstrate an understanding of the manufacturing requirements for the dental appliance design.

The dental appliance manufacturer shall ensure that amendments to prescriber requirements are adequately defined and documented.

The dental appliance manufacturer shall maintain a copy of all prescriptions and shall demonstrate that prescriber requirements are adequately reviewed.

4.4 Patient contact materials

4.4.1 Materials

Dental appliances shall be manufactured from materials that are fit for their intended purpose and use within the patient oral cavity. These materials shall have the inherent characteristics and properties to satisfy prescriber and dental appliance manufacturer requirements.

The dental appliance manufacturer shall identify and maintain a record of those patient oral cavity materials selected by the dental appliance manufacturer for use in the manufacture of dental appliances.

Where the dental appliance manufacturer's selection of a patient oral cavity material relies upon the material's conformance with an appropriate standard or conformity scheme for the material then a record shall be made of the appropriate standard or conformity scheme.

4.4.2 Subcontractor/supplier approval

The dental appliance manufacturer shall evaluate and select subcontractors/suppliers on their ability to supply the materials referred to in 4.4.1. Records of acceptable subcontractors/suppliers shall be maintained.

4.4.3 Purchasing

The dental appliance manufacturer shall maintain a documented procedure for purchasing those materials referred to in 4.4.1 from those acceptable subcontractors/suppliers referred to in 4.4.2.

4.4.4 Verification of purchased materials

The dental appliance manufacturer shall ensure that incoming purchased material is not used or processed until it has been verified as conforming with the applicable purchase order description and that it is undamaged. Nonconforming incoming purchased material shall be clearly identified by marking or attachment of a suitable label and shall be segregated from conforming materials.

The nonconforming incoming purchased material shall be disposed of by one of the following methods.

a) reworked to meet the specified requirement;
b) accepted with or without repair by concession;
c) re-graded for alternative applications; or
d) rejected or scrapped.

A record shall be made of the nonconforming material and the method of its disposal.

4.5 Defined manufacturing processes

The dental appliance manufacturer shall document the dental appliance manufacturing processes, connected with the dental appliances being manufactured, to allow an understanding of these processes.

The dental appliance manufacturer shall ensure that dental appliances are manufactured by suitably competent persons in conformity with the documentation referred to above.

Patient contact materials shall be processed in conformity with the generally accepted state of the art and the supplier's instructions for use or guidance.

Manufacturing equipment, and measuring and test equipment shall be used in accordance with the generally accepted state of the art and the equipment supplier's instructions for use or guidance.

Patient contact materials supplier's instructions for use or guidance, and equipment supplier's instructions for use or guidance, shall be available for reference purposes.

Nonconformity with the requirements for instructions for use and guidance referred to above is allowed if the absence of such instructions and guidance could not adversely affect or compromise the quality of the custom-made dental appliances being manufactured.

4.6 Training

The dental appliance manufacturer shall establish and maintain procedures for identifying training needs and provide for the training of all personnel carrying out dental appliance manufacturing and management system tasks.

Personnel shall be verified as competent to carry out assigned dental appliance manufacturing and management system tasks.

Records of training and competence in assigned tasks shall be maintained.

4.7 Maintenance and calibration of equipment

Manufacturing plant, manufacturing equipment and measuring and test equipment shall be suitably maintained and calibrated where appropriate. Records shall be maintained of maintenance carried out.

4.8 Cleanliness

The dental appliance manufacturer shall establish and maintain suitable procedures for the daily, weekly and monthly cleaning of the dental appliance manufacturer's manufacturing plant and equipment. Records shall be maintained of cleaning carried out.

4.9 Documented review of the final product

Each manufactured dental appliance shall be given a final inspection by a competent person to complete the evidence of conformance of the finished dental appliance with the prescriber's specified requirements. As a minimum, the final inspection of the finished dental appliance shall address the attributes specified in the DAMAS Final Inspection Checklist. See Annex E. Records shall be maintained to verify that final inspection has been carried out.

4.10 Defined handling and packaging

The dental appliance manufacturer shall establish and maintain procedures for handling, storage, packaging, preservation and delivery of finished dental appliances.

4.11 Control of records

The dental appliance manufacturer shall establish and maintain procedures for identification, collection, indexing, filing, storage, maintenance and disposition of quality records.

The system records identified under the appropriate clauses of this specification shall be maintained to demonstrate conformance to specified requirements and the effective operation of the management system.

Records shall be retained for a minimum period of 5 years.

4.12 Statement

Where appropriate, the dental appliance manufacturer shall draw up the statement containing the information stipulated in Section 2 of Annex VIII of the Medical Devices Directive - Statement concerning devices for special purposes.

In the case of Class IIA dental appliances, a copy of this statement shall be suitably attached to the finished dental appliance.

If the above is not appropriate, the dental appliance manufacturer shall draw up any required statement of conformity specified in appropriate Regulations. Where applicable, this statement shall be suitably attached to the finished appliance.

4.12.1 Patient Statement

Where appropriate when a custom-made device is supplied to a patient, the healthcare professional who writes the prescription shall ensure that the patient is aware that they may request the statement containing the information required by Sections 1 and 2 of Annex VIII and is made available to them on request.

The dental appliance manufacturer shall ensure that the statement is passed on with the custom-made device so that it may be made available to the patient on request.

4.13 Labelling

Where appropriate, each finished dental appliance shall be suitably labelled as specified in Section 13 of Annex I of the Medical Devices Directive. Information supplied by the manufacturer.

If the above is not appropriate, the dental appliance manufacturer shall suitably label each finished dental appliance as specified in appropriate Regulations.

4.14 Post Market Surveillance and Vigilance Reporting

Where appropriate the dental appliance manufacturer shall review and document post market surveillance and vigilance as specified in Section 5 of Annex VIII of the Medical Devices Directive. As a minimum this will be undertaken by 4.14.1 and 4.14.2.

4.14.1 Complaints

The dental appliance manufacturer shall establish and maintain a documented system for the effective handling of customer complaints and reports of dental appliance nonconformities.

Records of customer complaints, including the cause of complaints and the corrective action taken to alleviate complaints, shall be maintained.

4.14.2 Appliance Recall

The dental appliance manufacturer shall establish and maintain procedures for recalling appliances where it has been identified that the health and safety of a patient and where applicable, any other person, may be compromised by using the appliances.

4.15 Internal audits and management review

4.15.1 Internal audits

The management system shall be internally audited to verify that manufacturing process activities and system activities comply with planned arrangements. The internal auditing system shall be documented and records shall be maintained to verify that internal auditing has been carried out. As a minimum the system shall be audited internally once per year.

4.15.2 Management review

As a minimum, the dental appliance manufacturer shall annually review the dental appliance manufacturing system to ensure its continuing suitability and effectiveness in satisfying the requirements of this management system specification. As a minimum, the review shall consider the results of internal audits carried out as specified in 4.15.1. Records of management reviews shall be maintained.

Annex A List of normative references

This list describes the applicable directives and regulations that apply to the manufacture and placing on the market of custom-made medical devices at the publication date of this specification. Users of this specification should assure themselves that they are complying with the appropriate directives and regulations that apply in their country or trade area.

Country or trade area	Country or trade area specific	Generic specific
United Kingdom	The Medical Devices (Amendment) Regulations 2008 SI No 2936	Directive 2007/47/EC of the European Parliament and of the Council. Amending Council Directive 93/42/EEC concerning medical devices.
USA	U.S Code of Federal Regulations, FDA Quality Systems/Good Manufacturing Practices	

Country or trade area	Country or trade area specific	Generic specific

Annex B Guidance and explanatory notes

This annex provides guidelines and explanatory notes to help a dental appliance manufacturer establish and maintain a quality management system that will conform to the requirements of this specification. The guidelines and notes are not prescriptive and are not intended to imply uniformity in the structure of quality management systems or uniformity of documentation. The guidelines and explanatory notes are cross-referenced to the appropriate requirement clause in this specification.

NOTE 1 Manufacturers of custom-made medical devices (custom-made dental appliances) must comply with the statutory regulations that apply to their manufacture and placing on the market. Relevant statutory regulations are described in Annex A. These are not claimed to be exclusive and it is the dental appliance manufacturer's responsibility to identify and comply with the regulations that apply in their trading area(s).

4.1.1 Conformity policy
This may be met by a normal quality policy and quality objectives statement e.g. as required by ISO 9001 or by preparing a statement of conformity based upon the model statement of conformity shown in Annex D of this specification. It is good practice to display the statement of conformity within the laboratory so that it is open to public examination and as a reminder to employees about Regulations applying to the manufacture of custom-made dental appliances
4.1.2 Management representative
The management representative should be a member of the top management team, e.g. owner, partner, director, senior manager. For sole practitioners the owner will be the management representative. As a minimum, this person should be responsible for ensuring that the quality management system is periodically audited and reviewed by top management.
4.2.1 General
There should be some form of documentation kept available to allow an assessment of conformity with this specification. This is normally addressed by the use of documented plans and/or procedures and/or flow charts and/or checklists and/or forms and records. Standard practice would be to collate this documentation into a Manual for ease of reference. Note that part Annex VIII of The Medical Devices Directive requires the following: The manufacturer must undertake to keep available for the competent authority the following: *"For custom-made devices, documentation, indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performance of the products, including the expected performances, so as to allow assessment of conformity with the requirements of this Directive.* *The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph."* The EU Competent Authorities have not defined what must be documented to comply with the requirement in the above two paragraphs. Conforming to the requirements of this specification should allow a dental appliance manufacturer to comply with the requirements of this part of Annex VIII. Performances and expected performances may be addressed by the use of a generic statement for each type of custom-made dental appliance being manufactured. Dental appliance manufacturers should seek to develop these generic statements in co-operation with prescribers and other interested parties. The following examples have found general acceptance with the dental appliance manufacturing industry. **Custom-made prosthodontic appliance** A prosthodontic appliance attempts to re-establish the normal function and performance of a tooth, teeth, a missing tooth, or missing teeth, in a manner that attempts to maintain or improve upon the aesthetic features of the patient's oral cavity and/or teeth and/or face and/or articulation. A prosthodontic appliance attempts to carry out the normal function and performance of natural teeth, under typical oral environmental conditions, for a time specified by the prescriber, without causing any unacceptable biological, anatomical or psychological damage to the patient.

Custom-made orthodontic (includes devices such as bite raisers, bleaching trays, occlusal rehabilitation splints etc, that perform in a similar way to an orthodontic appliance)

The performance of an orthodontic appliance is to cause tooth movement for the treatment of malocclusion and/or the improvement of the aesthetic features of the patient's oral cavity and/or teeth and/or face. An orthodontic appliance is expected to perform as specified by the prescriber, under typical oral environmental conditions, for a time specified by the prescriber, without causing any unacceptable biological, anatomical or psychological damage to the patient. An orthodontic appliance is expected to keep to a minimum any discomfort the patient may undergo as a result of the prescribed treatment.

Custom-made nightguard dental appliance

A nightguard dental appliance attempts to treat, alleviate and minimise the discomfort arising from bruxism. A nightguard dental appliance is expected to perform as specified by the prescriber, under typical oral environmental conditions, for a time specified by the prescriber, without causing any unacceptable biological, anatomical or psychological damage to the patient. A nightguard dental appliance is not expected to cause any additional discomfort to the patient because of the prescribed treatment.

Custom-made splint

The performance of a splint is to provide mechanical support during splint therapy. The splint is expected to perform as specified by the prescriber, under the appropriate environmental conditions, for a time specified by the prescriber, without causing any unacceptable biological, anatomical or psychological damage to the patient. A splint is expected to keep to a minimum any discomfort the patient may undergo as a result of the prescribed treatment.

4.2.2 Legal and system documentation

Dental appliance manufacturers should ensure they know and understand the regulations that apply to their manufacturing facilities. Relevant references are given in Annex A.

4.2.3 Registration with the competent authority

Registration is normally carried out by completing and submitting a registration form to the competent authority when all regulatory requirements are met. The competent authority will normally provide a registration acknowledgement letter and reference number for administration purposes. This letter may be used to demonstrate conformity with the requirements of 4.2.3. Note that new dental appliance manufacturers must be complying with the requirements of the MDR and/or other appropriate Regulations and registered with the competent authority when they manufacture for the first time.

4.3 Documented review of the prescriber's requirements

A simple documented system or procedure should be established specifying how reviews of prescriber requirements will be controlled. This may consist of sub-systems or procedures that address the requirements under 4.3. The dental appliance manufacturer should:

a) State how the prescriber's prescription is reviewed to ensure that the design and manufacturing requirements are understood and documented.

b) State how pre-manufacturing processes such as special trays for second impression taking, study models, etc are controlled.

c) State how and where materials etc supplied by the prescriber for incorporation within the appliance to be manufactured will be recorded.

d) State what checks should be made before manufacturing will commence. A two-stage check is good practice, e.g. when the prescription arrives (check correct information supplied) and when models/dies, etc. are approved for the manufacturing process to commence. Checks should be carried out by a competent person and should normally require an approval signature before full manufacturing is commenced.

e) State how amendments to prescriptions will be agreed, recorded and authorised. Such a record should show revised instructions. An amendment record should be made when the prescriber authorises the use of poor models etc. Amendment approval should normally require the initials of the manufacturing person who has been responsible for processing and recording the amendment.

f) State how information and materials etc will be despatched to a subcontractor/ supplier, state what controls should be in place whilst manufacturing is taking place at the subcontractor/supplier, state what inspection should be carried out when the custom-made dental appliance is returned to the dental appliance manufacturer, state what should be done with nonconforming custom-made dental appliances.

g) State how prescriptions that have become damaged or unusable should be dealt with.

4.4.1 Materials

Satisfactory materials for use in contact with the patient body are commercially available from established suppliers to the trade. These suppliers have a duty of care to supply materials to the dental appliance manufacturer that are fit for purpose and of satisfactory quality. The dental appliance manufacturer should make a list of the materials they use. The materials are best listed by generic type, e.g. synthetic polymer teeth, dental casting gold alloy and/or brand name. The list of materials may be conveniently associated and linked in one document with the requirement for records of subcontractors/suppliers in 4.4.2.

In some trading areas, conformity schemes have been established to ensure that patient health and safety is not compromised by a patient contact material that is placed on the market, e.g. the European Union CE marking scheme. Conformity with such a scheme is a reasonable method for selecting materials but this method of selection is not mandatory. Other trading area conformity schemes may be appropriate, e.g. FDA in the USA.

4.4.2 Subcontractor/supplier approval

The following criteria may be used for evaluating and selecting subcontractors, suppliers and materials.

a) Capability to provide materials or accessories or custom-made dental appliances that meet the essential requirements of the Medical Devices Directive and, where applicable, are CE marked in conformity with this Directive.

b) Capability to provide materials or accessories that conform to national or international standards. Confirmation of this capability would normally include a certificate of conformity to the appropriate standard and/or criteria e).

c) History and reliability with similar materials or accessories or custom-made dental appliances.

d) Published experience of other users.

e) Maintenance of an independently registered and certified quality management system whose scope of registration addresses the materials or accessories or custom-made dental appliances to be procured.

f) Evaluation of samples of materials and/or accessories and/or processes and/or custom-made dental appliances.

Criteria a), b) and c) are usually used when developing a system. Criteria f) is usually used when considering the use of new subcontractors, suppliers and materials.

When evaluating subcontractors for the manufacture of custom-made dental appliances, it is good practice to examine the relevant competent authority registration documentation. In addition, the subcontractor should be encouraged to have a management system in place that conforms to the requirements of this specification and to be DAMAS registered.

4.4.3 Purchasing

A simple documented system or procedure should be established specifying how the purchasing of patient contact materials will be controlled. This may consist of sub-systems or procedures that address the requirements under 4.4.1, 4.4.2, 4.4.3 and 4.4.4. For example, a system for selecting suitable materials and suppliers of these materials, a system for specifying and approving purchase orders/documentation and a system for verifying purchased materials. It is usually beneficial to use this purchasing procedure for the purchase of non-patient contact materials.

4.4.4 Verification of purchased materials

It is imperative that the dental appliance manufacturer verifies that they have received the materials they have ordered and that the materials conform to specified requirements.

The dental appliance manufacturer should check the materials they have received and record that this checking has been done, usually by a signature on the retained copy of the purchase order. Similarly, the dental appliance manufacturer should record what they have done with nonconforming materials. See the methods for disposal of nonconforming materials in Clause 4.4.4 of the specification.

4.5 Defined manufacturing processes

Care should be taken when documenting custom-made dental appliance manufacturing processes as over-documentation can easily occur. The amount and level of documentation required for process control is usually determined by the level of competence required for personnel to carry out the processes. A general approach to setting up this type of documentation that will allow an understanding of manufacturing process, and to ensure that custom-made dental appliances are manufactured in accordance with this documentation is as follows:

a) Establish process flowcharts that simply describe the manufacturing process steps to produce custom-made dental appliances. The flowcharts should give a clear and simple understanding of the manufacturing processes concerned with the production of custom-made dental appliances. It is convenient to arrange the flowchart in the stages that a trainee would follow when being trained in the manufacturing process. This facilitates the recording of personnel training and competencies in manufacturing activities - see 4.6. Dental appliance manufacturers should seek to develop generic flowcharts in co-operation with prescribers and other interested parties. Cross-referencing to technical books on dental appliance manufacturing may also be useful.

b) Establish and document your procedures and methods for ensuring that relevant documentation, e.g. prescription forms, job cards, work tickets, etc. is controlled and completed during each manufacturing stage

c) Establish a system for keeping suppliers materials instructions for use or guidance under control. This is desirable for keeping evidence in case of a "generally accepted state of the art" defence. It is good practice to collate all the information provided by suppliers of materials and equipment that gives instructions in the use of these materials and equipment. This collated information should be made available to the appropriate staff for reference purposes. However, attention should be made to the notes below.

d) Establish how traceability between the patient and prescriber is maintained. In most instances, this may be facilitated by a suitable marking on models etc. In many cases a code may be used to protect the identity of the patient but there should be some system for reconciling the code with the patient's identity at the end of the manufacturing process.

e) Where appropriate, e.g. medium to large dental laboratories, examine each flowchart step and decide if an in-process inspection is needed. If in-process inspection is needed, then specify the inspection and tests to be carried out, the records to be made, what to do if the custom-made dental appliance fails the inspection and the authorisation initial required to proceed to the next manufacturing process.

f) Establish a simple documented system or procedure specifying how nonconforming custom-made dental appliances will be controlled should be established. In practice and due to the nature of custom-made dental appliance manufacturing, personnel carrying out particular manufacturing processes readily identify and correct nonconforming custom-made dental appliances as they occur. Normally by making the correction themselves or by returning the work to the appropriate competent person for correction.

g) Establish a system for when this type of correction isn't possible. In this situation, the custom-made dental appliance should be clearly marked as nonconforming by attachment of a suitable tag or label or record on the prescription. The nonconforming custom-made dental appliance should be brought to the attention of a responsible person who should then determine what corrective action is needed to dispose of the nonconformity. A summary of the corrective action taken should be recorded. The disposition of nonconforming custom-made dental appliances that are detected after delivery or use should be treated similarly or by application of a complaint procedure. See 4.14.

NOTE 1 In some instances, the supplier may not provide materials instructions for use or guidance if the materials may be safely used without any such instructions. For example, Class I and Class IIA medical devices. Materials typically supplied to the industry are in these categories.

NOTE 2 Custom-made dental appliance manufacturers may work away from supplier materials instructions for use or guidance providing they do this using methods that are sensible and readily achievable by competent personnel working to the generally accepted state of the art. Custom-made dental appliance manufacturing processes are special and require competent personnel to carry out these processes. During the training of personnel in special processes, personnel will be instructed and trained in the general methods of carrying out a process. Personnel will also be instructed in the variations that may be made to these general methods and the supplier's instructions for use without the quality or acceptability of the process output being compromised. For example, mixing ratios of plaster and water may be varied depending upon the type and number of models being cast at one time. Variation from the recommended ratios is being made but the resulting models will be fit for purpose in the next manufacturing process. This rule may be applied in general throughout the whole dental appliance manufacturing process.

NOTE 3 Personnel who have been designated as being competent to carry out particular manufacturing processes will understand and know the limits of variation that can be made to particular processes and material processing parameters without compromising the quality or acceptability of the particular process. It will be clear to other competent persons if the previous manufacturing process or processes had not been carried out within the generally accepted state of the art. This is how a dental laboratory will generally control working away from a supplier's instructions and guidance and is the generally accepted method within the industry.

4.6 Training

The manufacture of an acceptable custom-made dental appliance can only be achieved by people with special personal attributes. With these special personal attributes, they can process, fabricate and manipulate materials, to the dental appliance design requirements, specified by the prescriber. These special personal attributes are a combination of manual dexterity, an eye for detail, an appreciation of the aesthetic and artistic qualities required of a dental appliance, and the skills and knowledge achieved through training in dental laboratory practices, i.e. primarily on-the-job training.

A simple documented system or procedure should be established specifying how personnel training and competency will be controlled and recorded. The system should address as appropriate, pre-employment trade tests, induction training, formal academic training, training and competency in manufacturing and management system tasks, including the use of associated computer software. Management should verify the training and competency of personnel in relevant manufacturing and/or management system tasks, particularly personnel reviewing prescriber requirements and final inspection.. This is usually achieved by establishing an individual training record for each member of staff. This staff training record should also contain confirmation by the individual concerned that they have been trained in the relevant manufacturing and/or management system tasks.

4.7 Maintenance and calibration of equipment

A simple documented system or procedure should be established specifying how essential maintenance and appropriate calibration will be controlled and recorded.

Periodic condition surveys of manufacturing plant, manufacturing equipment and measuring and test equipment is normally sufficient to ensure continuing process capability. Providing appropriate corrective and preventive action is taken when faults are found, or when a breakdown occurs, and that appropriate maintenance records are maintained. A planned preventive maintenance schedule is not normally appropriate for an organization manufacturing custom-made medical devices. Similarly, calibration of measuring and test equipment is not normally appropriate, as it is readily apparent to a competent person when such equipment is not functioning correctly. The appearance and form of the processed device is a more reliable indicator that a process has been carried out correctly.

In general terms, custom-made dental appliance-manufacturing equipment can only be subjected to simple essential maintenance by the dental appliance manufacturer, any other maintenance will require the services of a specialist. A simple periodic condition survey of equipment and plant is sufficient in these manufacturing circumstances.

It is good practice to document the grounds for not calibrating measuring and test equipment where there is considered to be little risk in not doing so. The following grounds have been found useful in the manufacture of custom-made dental appliances.

"Dimensions, areas, proportions, sizes, measurements and aesthetic properties, described on a prescription, are for guidance only. Primarily because making definitive measurements within the oral cavity is not possible. This is due to the suppleness of tissue within the oral cavity and the natural unevenness of oral surfaces and teeth. Consequently, measuring equipment that the dental laboratory uses to measure dimensions, areas, proportions, sizes or aesthetic properties of dental appliances is "FOR INDICATION ONLY" and does not require calibration to national standards."

"The dental laboratory will manufacture a dental appliance, to a prescription, using its knowledge and experience of the appliance in question. The dental laboratory will take account of the prescription guidance regarding dimensions, areas, proportions, sizes, measurements and aesthetic properties, described on the prescription, but may adjust this as necessary to ensure that the manufactured appliance does not compromise the patient's health and safety and that it is fit for purpose."

"Oral cavity materials that require physical and/or chemical processing before being suitable for incorporation in a dental appliance will be processed according to the guidance given in the manufacturer's instructions. The physical and/or chemical process parameters, e.g. time, temperature, pressure, chemicals ratio, given by the manufacturer are indicative measures only. The characteristics and properties of the materials are such that they are "self calibrating" in terms of physical and/or chemical process requirements."

"In practical terms, oral cavity materials that have been physically and/or chemically processed as advised, can be verified as correct, by a competent person carrying out a visual and physical inspection of the processed material. If the materials have not been physically and/or chemically processed as advised, then it will be readily apparent to a competent person that the processed materials are unacceptable by their form and appearance."

"Consequently, measuring equipment, used by the dental laboratory to determine or set physical and/or chemical process parameters, is "FOR INDICATION ONLY" and does not require calibration to national standards."

However, if there is a clear need for calibration of certain equipment then this should be addressed and documented using ***BS EN ISO 10012: 2003 Measurement management systems - Requirements for measurement processes and measuring equipment as a guide.*** Expert advice should be taken if the dental appliance manufacturer is considering implementing a measurement management system such as this because major problems may arise if such a system is not implemented correctly.

4.8 Cleanliness

A simple documented system or procedure should be established specifying how manufacturing plant and equipment should be cleaned at the specified frequencies and recorded. A simple log sheet should be developed that specifies the areas to be cleaned, the persons with responsibility for cleaning, the cleaning frequencies and space for recording (initials) that cleaning has been carried out correctly.

NOTE 1 The MDD specifies that manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient or user. There is no requirement for laboratories to sterilise their products. So long as the manufacturing area is kept reasonably clean and appliances are socially clean after manufacture then there should no risk of cross-infection to the patient or user. Before fitting a custom-made dental appliance to a patient, the prescriber has a duty of care to ensure that the appliance is socially clean and will not compromise the health and safety of the patient. It should be recognised that the oral cavity itself is only socially clean in that it will contain bacteria, viruses, spores and fungi etc associated with the local environment, foodstuffs, drinks and social contact.

NOTE 2 Clean can be defined as free from dirt, marks or stains and socially clean as being free from dirt but not necessarily marks or stains. Cleaning is a process which removes soil and a high proportion of infectious agents by washing with a solvent (usually water and detergent) which may be heated. Cleaning can be achieved by either manual or automated means.

4.9 Documented review of the final product

A simple documented system or procedure should be established specifying how final inspection should be controlled and recorded. The following should be addressed

The person who does the final inspection should be competent to do so. Usually this will be a fully trained and competent technician who has the experience to decide whether a manufactured custom-made dental appliance complies with the prescription requirements. The person carrying out the final inspection should inspect the appliance to ensure conformity with the prescription and where applicable with the relevant requirements of an industry final inspection checklist.

The person carrying out the final inspection should also inspect the prescription and other documentation, e.g. work tickets, to verify that all other specified inspections have been carried out correctly. The result of the final inspection should be recorded and authorised. The simplest place to keep the evidence of a final inspection is by an authorised signature on the prescription.

If the appliance is nonconforming either due to not meeting prescription requirements and/or other specified inspections have not been carried out correctly then the appliance should be brought to the attention of a responsible person who should then determine what corrective action is needed to dispose of the nonconformity. A summary of the corrective action taken should be recorded.

4.10 Defined handling and packaging

A simple documented system or procedure should be established specifying how the handling, storage, packaging, preservation and delivery of finished custom-made dental appliances will be controlled. This may be addressed by establishing a simple matrix for each custom-made dental appliance type, e.g.

Custom-made dental appliance type	Handling precautions	Storage area	Packaging system	Preservation precautions	Delivery method

4.11 Control of records

A simple documented system or procedure should be established specifying how records will be controlled. Records must be retained for five years although it may be prudent to keep records for a longer period, as there may be other consumer protection regulations that may require the dental appliance manufacturer to keep records for a longer period. A simple matrix helps to clarify record keeping.

Record	Responsibility for record	Record location	Record retention time

Typical records are: Obsolete Management System Documentation, Completed Prescriptions, Approved Materials and Suppliers List, Materials and/or Process Evaluation Forms, Obsolete Approved Materials and Suppliers List, Purchase Orders and Materials Receipt, Materials, Accessories, and Equipment Information, Obsolete Materials Accessories, and Equipment Information, Maintenance Logs, Cleaning Logs, Staff Training Records, Complaints Log and Correspondence, Internal Audit Checklists and Results, Results of Management Reviews.

4.12 Statement

The Medical Devices Directive requires the manufacturer to draw up a statement of conformity - Section 2 of Annex VIII of the Directive. If the device is Class IIA or Class IIB or Class III then this statement must accompany the device. It is satisfactory for a statement to be sent if not legally required, e.g. with a Class I device or for it to be part of another document or for it to be an integral part of an invoice or label or work ticket or any combination. It is important that the correct words are used.

It is suggested that the following text be added to the statement of conformity when the dental appliance incorporates materials etc supplied by the prescriber.

"In the event that the prescriber has supplied some of the materials etc for incorporation in a particular custom-made dental appliance then this appliance cannot be guaranteed to fully meet with the applicable relevant essential requirements.

The grounds for placing such a device on the market is that the risk of compromising the patient's health and safety by using materials etc supplied by the prescriber is assessed as minimal. This risk assessment relies upon a duly qualified medical practitioner's competence and duty to supply materials etc that is either from a CE marked source or from an appropriate European Competent Authority registered manufacturer of custom-made medical devices."

The text above may be incorporated within the dental appliance manufacturer's statement of conformity or in label form.

4.12.1 Patient Statement

The Medical Device (Amendment) Regulations 2007 regulation 9 states that:

When a custom-made device is supplied to a patient, the healthcare professional who writes the prescription for the custom-made device shall, in relation to each patient that they supply with such a device:

- Ensure that the patient is aware that they may request the statement containing the information required by Sections 1 and 2 of Annex VIII; and
- Ensure that the statement containing the information required by sections 1 and 2 of Annex VIII is made available to the patient on request.

In addition (as stated in regulation 15) it is the manufacturer's responsibility to ensure that the statement is passed on with the custom-made device so that it may be made available to the patient on request.

To meet the requirements you must include the following information on the 'patient statement':

- Name & Address of the Laboratory
- 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 clinic
- The statement of conformity, i.e. "This is a custom-made medical device that has been manufactured to satisfy the design characteristics and properties specified by the prescriber for the above named patient. This medical device is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex I of the Medical Devices Directive and the United Kingdom Medical Devices Regulations".

If you choose to issue a triplicate copy of the prescription as your 'patient statement' bear in mind the quality of the prescription i.e. the copy is presentable and information is legible.

For further guidance on the information required in the patient statement contact the Dental Laboratories Association who can provide an example.

4.13 Labelling

Custom-made dental appliances must be labelled as specified in the Medical Devices Directive. As a minimum the following information should be on the label

- The name or trade name and address of the manufacturer.

- The details strictly necessary to identify the device and the contents of the packaging especially for the users.

- The words 'custom-made device'.

- Any special storage and/or handling conditions.

- Any warnings and/or precautions to take.

The label may be an integral part of another document, e.g. returned lab ticket, invoice/delivery note, etc. There are generally no special storage or handling conditions other than perhaps keep away from extreme heat or cold and there is generally no need for warnings/precautions. Appliances do not need to be marked non-sterile.

4.14 Post Market Surveillance and Vigilance Reporting

As specified in Section 5 of Annex VIII of the Medical Devices Directive all manufacturers of custom made devices must undertake to review and document experience gained in the post-production phase and to implement appropriate means to apply any necessary corrective action. *This can be achieved by implementing the complaints procedure detailed in 4.14.1. And the recall procedure detailed in 4.14.2.*

4.14.1 Complaints

A simple documented system or procedure should be established specifying how complaints will be managed and resolved. However, before establishing such a system or procedure, the dental appliance manufacturer should set some criteria for designating what constitutes a complaint or nonconformity in the context of manufacturing a custom-made dental appliance. The formal definitions for complaints and nonconformities are given in Clause 3 of this specification and it is the responsibility of the dental appliance manufacturer to decide when these circumstances arise.

The following approach is recommended:

a) Establish a documented generic complaint procedure for resolving both complaints and reports of nonconformity. That is, process a justified report of nonconformity as a complaint.

b) Review any adverse communication made about an appliance. An adverse communication may be defined as "A transmission of information that is contrary to your interests or welfare or is harmful or unfavourable to your organisation".

c) Determine if the adverse communication should be considered as a ***possible complaint*** or ***a possible report of nonconformity***. If the adverse communication is not considered a possible complaint or possible report of nonconformity then process as a normal communication. Do not implement your complaint procedure.

NOTE 1: A ***possible report of nonconformity*** may be defined as an appliance that, on re-inspection, the prescriber or dental appliance manufacturer believes would fail the DAMAS final inspection criteria and any other relevant inspection criteria for the appliance in question. For example, if an appliance didn't fit the model, if models didn't occlude correctly, if porcelain had cracks and porosity, if acrylic work had processing faults, if fitting surfaces were rough, if there were carbon inclusions etc.

NOTE 2: A request for a remake, or a statement that the appliance does not fit the patient should not necessarily be interpreted as a report of nonconformity or a complaint. For example, a prescriber may return an appliance that does not fit the patient. In the prescriber's view, this is a nonconformity. But the appliance may have fit the model when it was made and the dental appliance manufacturer's opinion is that the appliance is not a nonconformity

NOTE 3: A prescriber may return an appliance and/or other entities for remake without any indication as to whether or not they are complaining or reporting a nonconformity. Or a prescriber may make some comment about the quality or fitness of an appliance but may not be making a complaint about the appliance. In these situations it is the dental appliance manufacturer's decision as to whether or not he treats them as a complaint or a report of nonconformity. In most cases it would be better to treat these situations as unjustified complaint/nonconformity so that records are available for analysis and identification of prescribers who are frequently asking for remakes.

d) Record the name of the prescriber and details of the possible complaint/possible report of nonconformity.

e) Define responsibility for resolving the possible complaint/possible report of nonconformity.

f) Decide if the possible complaint/possible nonconformity is justified.

g) If the possible complaint/possible nonconformity is unjustified, tell the prescriber that you do not agree with their allegation and come to some acceptable arrangement for the prescriber and dental appliance manufacturer.

h) If the possible complaint/possible nonconformity is justified, process both as a complaint.

i) Find out what has caused the complaint and decide the corrective action needed. Record the corrective action.

j) Tell the prescriber how the dental appliance manufacturer is going to correct the complaint.

k) Where appropriate, follow up the complaint to ensure that it has been resolved satisfactorily. For example, the immediate action to resolve the complaint might be to remake but to ensure the complaint doesn't arise again, further action might be required to eliminate the cause of the complaint.

l) Periodically analyse complaints to see if the dental appliance manufacturer can prevent them happening in the future. Implement and review this preventive action as necessary.

m) Re-analyse to see if the dental appliance manufacturer has eliminated the complaints.

4.14.2 Appliance Recall

Manufacturers have an obligation to notify the relevant competent authorities of the following incidents immediately on learning of them and the relevant actions:

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

For dental laboratories to achieve this clause a simple documented procedure should be established detailing how appliances will be recalled using the following guidelines as a minimum:

- Detail how the prescriber(s) shall be notified i.e. telephone/fax and then by formal letter.
- What details will be included in the formal correspondence i.e. name and address of the prescriber, the patients affected, details of the appliances that are suspect and the reason for the recall.
- If the laboratory has been informed, by a third party, that they have been supplied with suspect materials that could have affected the health and safety features of appliances the laboratory has manufactured, details of how the laboratory will act on this information together with how they will inform the prescriber.
- How the laboratory will inform the relevant authorities should this need arise.

4.15. 1 Internal Audits

A simple documented system or procedure should be established specifying how internal audits should be controlled.

The MDD requires that a dental appliance manufacturer should take all measures necessary to ensure that the manufacturing process produces custom-made dental appliances that are manufactured in accordance with the relevant documentation. This may be verified by carrying out internal audits of the management system. The following approach is suggested

The person who has implemented the system should audit the system using this specification as an audit checklist. In the majority of cases, this person will be the management system representative. The management system representative may then train others in internal auditing.

Set a plan of internal audits of the system to verify that you are doing what you said you would.

Derive an internal audit checklist(s) that addresses all the essential system activities and develop this checklist(s) as experience is gained with internal auditing.

Carry out the internal audits. Use an independent person wherever possible, e.g. office staff not directly involved with the system. Use of an independent person will be difficult for a sole trader, or a small dental appliance manufacturer, and in these instances, it is recommended that the management system representative carry out the internal audits.

Record nonconformities, i.e. what is not being done correctly.

Determine out what has caused the nonconformities and record.

Determine corrective action needed to fix the nonconformities and record.

Determine any follow-up action needed to verify the corrective action has been effective.

Report the results of the internal audit to management as applicable.

For further guidance see ISO 19011 Guidelines on quality and/or environmental management systems auditing.

4.15.2 Management review

A simple documented system or procedure should be established specifying how management reviews will be controlled. Top management should review the results of internal audits to see if the system is working correctly and/or if opportunities exist to improve the system. Management 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.

The following elements should be addressed at management reviews.

Results of internal audits carried out.

Results of any third party assessments since the last review.

Analysis of customer complaints and customer satisfaction since the last review.

Performance and continuing acceptability of suppliers.

Staff training requirements.

Assessment of the system's effectiveness in achieving the quality/conformity policy and any other appropriate quality objectives.

Assessment of the need for action that will prevent or minimise the risk of quality problems occurring.

Assessment of the need for updating the system brought about by new technologies, quality concepts, market strategies and social or environmental conditions.

Annex C Guide to the essential requirements and conformity assessment procedures

Article 3 of the Medical Devices Directive specifies that medical devices must meet the essential requirements set out in Annex I of the Medical Devices Directive which apply to them, taking account of the intended purpose of the devices concerned. Annex I is in two parts.

I GENERAL REQUIREMENTS

All of these requirements (1-6). For custom-made medical devices, the prescriber is ultimately responsible for the final design of the device, even though the manufacturer may have provided significant design input.

II REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

Listed here the requirements judged to be applicable and those that are not. The judgements made are not to be seen as definitive. It is the manufacturer's responsibility to decide which essential requirements apply to the medical device they are manufacturing. It is the manufacturer's responsibility to defend their decision if challenged by the relevant national competent authority. The manufacturer must satisfy themselves that they have taken all reasonable precautions and exercised due diligence to ensure that the medical devices they manufacture meet the relevant essential requirements specified in the Directive.

SUGGESTED OBLIGATORY REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

The requirements of each section are specified in the Medical Devices Directive.

Section	Applicable	Comments	Section	Applicable	Comments
7.1	Yes		12	No	
7.2	Yes		13.1	Yes	
7.3	Yes		13.2	No	
7.4	No		13.3 a	Yes	
7.5	Yes		13.3 b	Yes	
7.6	Yes		13.3 c	No	
8.1	Yes		13.3 d	No	
8.2	No		13.3 e	No	
8.3	No		13.3 f	No	
8.4	No		13.3 g	Yes	
8.5	No		13.3 h	No	
8.6	Yes		13.3 i	Yes	
8.7	No		13.3 j	No	
9.1	Yes		13.3 k	Yes	
9.2	Yes	Para Indent 1	13.3 l	No	
9.3	No		13.3 m	No	
10.1	No		13.3 n	No	
10.2	No		13.4	No	
10.3	No		13.5	No	
11	No		13.6 a to q	No	See 13.1 last para

In addition, a manufacturer of custom-made medical devices must follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before placing each device on the market.

In essence Annex VIII requires the following:

First Requirement

A statement is required from the manufacturer that must contain the following information:

the name and address of the manufacturer.

data allowing identification of the device in question.

a statement that the device is intended for exclusive use by a particular patient together with the name of the patient.

the name of the medical practitioner or other authorised person who made out the prescription and, where applicable, the name of the clinic concerned.

the specific characteristics of the product as indicated by the prescription.

a statement that the device in question conforms to the essential requirements set out in Annex I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds.

NOTE: In the case of Class II custom-made medical devices, this statement must accompany the device when it is placed on the market.

Second Requirement

The manufacturer must undertake to keep available for the competent authority the following:

For custom-made devices, documentation, including manufacturing site(s) and allowing an understanding of the design, manufacture and performance of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Directive.

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the paragraph above.

Third Requirement

Information contained in the declaration concerned by this Annex VIII (in effect the *Second Requirement* above) must be kept for at least five years.

Forth Requirement

For custom-made devices, the manufacturer must undertake to review and document experience gained in the post-production phase. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and the relevant corrective actions:

- any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or

might have led to the death of a patient or user or to a serious deterioration in his state of health;

- any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

Fifth Requirement

The finished custom-made medical device must be suitably labelled to meet the requirements of the Directive. As a minimum the following data will be required:

the name or trade name and address of the manufacturer.

the details strictly necessary to identify the device and the contents of the packaging especially for the users.

the words 'custom-made device'.

any special storage and/or handling conditions.

any warnings and/or precautions to take.

NOTE: See First requirement above. It is usual to combine the statement requirement with the labelling requirement.

Sixth Requirement

A manufacturer of ‘custom-made’ devices must register his business with the UK Competent Authority with a description of the devices concerned and his business address.

DAMAS SPECIFICATION

Clause 4 of the DAMAS Specification contains fifteen sub-clauses that specify the requirements that must be satisfied by a custom-made dental appliance manufacturer before they can become a DAMAS Registered Dental Appliance Manufacturer.

Sub-clauses 4.1 to 4.15 of Clause 4 have been designed to allow conformity with the “essential requirements” and “Annex VIII” of the MDD to be demonstrated to others.

The matrix overleaf demonstrates the relationship between the MDD requirements and the sub-clauses 4.1 to 4.15 of the DAMAS Specification.

MATRIX OF MEDICAL DEVICES REQUIREMENTS AND THE DAMAS SPECIFICATION															
REQUIREMENT	MET BY DAMAS SPECIFICATION SUB-CLAUSE(S)														
I General	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15
1	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2			✓	✓	✓				✓						
3			✓	✓	✓	✓	✓	✓	✓	✓					
4			✓	✓	✓	✓	✓	✓	✓	✓					
5			✓	✓	✓	✓	✓	✓	✓	✓					
6			✓	✓	✓	✓	✓	✓	✓	✓					
6a			✓	✓	✓									✓	✓
II Design and Construction	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15
7.1			✓	✓	✓	✓	✓	✓	✓	✓					
7.2			✓	✓	✓	✓	✓	✓	✓	✓					
7.3			✓	✓	✓	✓	✓	✓	✓	✓					
7.5			✓	✓	✓	✓	✓	✓	✓	✓					
7.6			✓	✓	✓	✓	✓	✓	✓	✓					
8.1			✓	✓	✓	✓	✓	✓	✓	✓					
8.6										✓					
9.1			✓		✓				✓	✓		✓	✓		
9.2			✓	✓	✓				✓						
13.1													✓		
13.3a												✓	✓		
13.3b												✓	✓		
13.3g													✓		
13.3i													✓		
13.3k													✓		
Conformity assessment	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15
1st Requirement												✓			
2nd Requirement	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3rd Requirement											✓				
4th Requirement														✓	
5th Requirement													✓		
6th Requirement		✓													

Annex D Model statement of conformity

This declaration has been drawn up to meet the specified requirements of the DAMAS Management System Conformity policy

DECLARATION OF CONFORMITY

The manufacturer

XYZ Dental Appliance Manufacturer
123 Any Street
Any Town
Any Post Code

declares that the manufacture of dental appliances described hereafter;

Prosthodontics and Orthodontics

is in conformity with the provisions of Directive 2007/47/EC of the European Parliament and of the Council amending Council Directive 93/42/EEC concerning medical devices, the provisions of the Medical Devices (Amendment) Regulations 2008 SI No 2936 and the requirements of the DAMAS Management System Specification

Done at: XYZ Dental Appliance Manufacturer, 123 Any Street, Any Town, Any Post Code

Date _____

Signed _____ A N Other Chief Executive

Annex E DAMAS final inspection checklist

MUTUAL POINTS:

1. Check prescription has been followed correctly
2. Fit of appliance to model is accurate
3. Check that models occlude correctly
4. Check that models are clean and presentable
5. Check that item of work has been cleaned in accordance with manufacturing procedures
6. Ensure job is booked out to the correct client.
7. Check packaging and correct dispatch date and time

CROWN & BRIDGE:

1. Check that there is a good overall fit of work to the die and model
2. Check that contact points and bite follow the dentists requirements
3. Check porcelain for faults such as cracks and porosity
4. Check the shade, glaze and anatomical form
5. Check that metalwork has been correctly polished

ORTHODONTICS:

1. Check all functional appliances on the articulator
2. Check acrylic work for processing faults
3. Check all wire components for damage and accuracy of fit, and that screws and springs are aligned and working correctly.
4. Check that acrylic bases are trimmed to the correct angles and are the correct thickness.
5. Ensure that all areas of acrylic and wire components have been polished correctly including soldered and welded joints

PROSTHETICS:

1. Check acrylic for processing faults such as porosity, movement of teeth and inclusion of foreign bodies.
2. Check the fitting surface of the appliance for any rough or sharp points
3. Ensure that the post dam is correctly positioned according to instructions
4. Check for correct depth in buccal, labial, lingual and palatal areas, check that all muscle attachments have been correctly trimmed, check that all edges of the appliance are rounded.
5. Check that acrylic has been polished correctly and all traces of plaster have been removed

CHROME COBALT:

1. Check that design is correct according to instructions supplied
2. Check that there are no pointed or sharp edges and clasps are clear of the bite
3. Check that acrylic retention areas are correctly cleared to take acrylic
4. Check the surfaces of chrome for any casting faults
5. Check that there is a high lustre polish where necessary and that the appliance is free from traces of investment and carbon inclusions.