DAMAS INTERNATIONAL LTD

DENTAL APPLIANCE MANUFACTURERS AUDIT SCHEME (DAMAS)

DAMAS

Dental Appliance Manufacturers Audit Scheme

MANAGEMENT SYSTEM SPECIFICATION

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Amendments issued since publication

Amendment No.	Date	Text affected
1	**01.01.2021**	**Introduction –** Addition of new implementation date which was delayed due to Coronavirus pandemic. References updated to include UK MDR (as amended).
2	**01.01.2021**	**4.1.1 -** References updated to include UK MDR (as amended).
3	**01.01.2021**	**4.2.3 -** Remove reference to European Union.
4	**01.01.2021**	**4.12 -** References updated to include UK MDR (as amended).
5	**01.01.2021**	**4.13 -** References updated to include UK MDR (as amended).
6	**01.01.2021**	**4.14.3 –** Remove reference to EU MDR 87(1).
7	**01.01.2021**	**4.15 –** Remove reference to EU MDR.
8	**01.01.2021**	**Annex A -** References updated to include UK MDR (as amended).
9	**01.01.2021**	**Annex B –** Updated to included refences to EU/NI authorised representative. Addition of refence to UKCA marking.
10	**01.01.2021**	**Annex B, 4.12, 4.12.1, 4.13, 4.14.3 and 4.15 -** References updated to include UK MDR (as amended).
11	**01.01.2021**	**Annex C -** References updated to include UK MDR (as amended).
12	**01.01.2021**	**Annex D -** References updated to include UK MDR (as amended).

0 Introduction

DAMAS International Ltd has produced this specification. By complying with the requirements of this specification, a dental appliance manufacturer can demonstrate that they have the capability to manufacture custom-made dental appliances in compliance with 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 **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 manufacturer's responsibility to meet the requirements.

NOTE 2 The requirements specified in Issue 8 of the DAMAS Management System Specification have been updated to reflect the amendments required within the Medical Devices Regulations 2017 and the UK Medical Devices Regulations 2002 (as amended). It is the responsibility of each dental appliance manufacturer to ensure they meet these amended requirements.

NOTE 3 Changes to Issue 7 have been made:

- Update references to the MDR 2017 and UK MDR as detailed in Annex A.
- Person responsible for compliance (4.1.2).
- Approval for manufacture – verification by a dental technician (4.3).
- Materials – to update the requirement for patient contact material documentation to be reviewed annually (4.4.1). To include a specific clause for traceability (4.4.5)
- Cleaning – to update the requirement for the manufacturer to have an infection control policy (4.8).
- Control of records – retention time updated to 10 years (4.11).
- Statement of conformity – update to wording requirements (4.12).
- Update the requirements of Post-Market Surveillance to include PMCF & PSUR (4.14).
- Addition of a requirement for Risk Management (4.15)

NOTE 4 For the purpose of DAMAS Registration, dental appliance manufacturers shall comply with the requirements specified in Issue 8 of the DAMAS Management System Specification by 25th May 2021.

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 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 Regulations.
Custom-made medical device	As defined in the Medical Devices Regulations.
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 authorised by virtue of their professional qualifications. (For the purposes of this specification, the term *customer* is synonymous with the term *prescriber*.)
Competent/Competence	Demonstrated ability by appropriate qualification and/or training to apply appropriate knowledge and skills.
Nonconformity	Non-fulfilment of a requirement.
Prescription	Information allowing an understanding of the prescriber's requirements for a custom-made medical device.
Dental Technician	General Dental Council, or where applicable, other appropriate National Regulatory Authority-registered dental professional who makes dental devices to a prescription from a dentist or clinical dental technician.

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 Regulations (MDR and UK MDR) and Dental Appliance Manufacturers Audit Scheme (DAMAS). Where appropriate, the commitment to conformance with the 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 Person responsible for regulatory compliance

Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their requisite expertise by at least two years of professional experience within the relevant field of manufacture.

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 Competent Authority or with the appropriate National Regulatory Authority. 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 pre-manufacturing approval for manufacture has been completed and documented by a dental technician to ensure that the dental appliance manufacturer can commence with manufacturing the prescribed appliance.

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 for the length of time indicated within the Medical Devices Regulations.

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. The record of patient oral cavity materials shall be reviewed and maintained annually.

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, 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.

4.4.5 Traceability

The dental appliance manufacturers shall ensure that selected patient contact materials referred to in 4.4.1 for use in the manufacture of a custom-made medical device are traceable to a particular purchase order or other appropriate system.

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

Patient contact materials supplier's guidance/instructions for use and equipment supplier's guidance/instructions for use 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/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.

The dental appliance manufacturer shall establish a documented procedure for dental laboratory infection control.

4.9 Documented review of the final product

Each manufactured dental appliance shall be given a final inspection by a dental technician 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 10 years.

4.12 Statement

Where appropriate, the dental appliance manufacturer shall draw up the statement containing the information stipulated in Section 1 of Annex XIII of the EU Medical Devices Regulations and/or the information referred to in paragraph 1 of Section 13 UK MDR (as amended).

In the case of custom-made 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

Custom-made devices shall be accompanied by the statement referred to in clause 4.12 which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

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.

4.13 Labelling

Where appropriate, each finished dental appliance shall be suitably labelled as specified in Chapter III of Annex I of the Medical Devices Regulations and/or Part 3 of the UK MDR (as amended).

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

4.14.1 Post-market clinical follow-up (PMCF)

The manufacturer shall undertake to review and document experience gained in the postproduction phase and to implement appropriate means to apply any necessary corrective action.

The manufacturer shall gather data on the manufactured appliance, including customer complaints and remakes, customer feedback, product and literature review, regulatory review and communications.

The manufacturer shall have a documented PMCF plan which shall specify the methods and procedures to proactively collect and evaluate clinical data with the aim of confirming the safety and performance of the device throughout its expected lifetime.

4.14.2 Complaints and appliance nonconformity

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 and appliance nonconformities, including the cause and the corrective action taken to alleviate complaints and appliance nonconformities, shall be maintained.

4.14.3 Appliance recall and reporting

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. This undertaking shall include an obligation for the manufacturer to notify the competent authorities of any serious incidents and/or field safety corrective actions immediately on learning of them.

4.14.4 Periodic safety update report (PSUR)

The dental appliance manufacturer shall prepare a PSUR for each device and, where relevant, for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan, together with a rationale and description of any preventive and corrective actions taken. The PSUR shall be documented annually by the dental appliance manufacturer.

4.15 Risk management

Dental appliance manufacturers shall establish, implement, document and maintain a risk management system.

Risk control measures adopted by the manufacturer for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage risks so that the residual risk associated with each hazard, as well as the overall residual risk, is judged acceptable.

The manufacturer shall inform users of any residual risks.

4.16 Internal audits and management review

4.16.1 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.

4.16.2 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 4.16.1. 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.

1. Regulation (EU) 2017/745 of The European Parliament and of the Council of 5 April 2017 On Medical Devices.
2. UK Medical Devices Regulations (as amended)

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 do not claim 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 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 of regulations applying to the manufacture of custom-made dental appliances.
4.1.2 Person responsible for regulatory compliance
The person responsible for regulatory compliance and/or 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, the person responsible for regulatory compliance shall demonstrate their requisite expertise by at least two years of professional experience within the relevant field of manufacture.
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 section 2 and 3 of Annex XIII of the Medical Devices Regulation requires the following: *The manufacturer shall undertake to keep available for the competent national authority's documentation that indicates its manufacturing site or sites and allows an understanding to be formed of the design, manufacture and performance of the device, including the expected performance, so as to allow assessment of conformity with the requirements of this regulation.* *The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which are manufactured in accordance with the documentation referred to in Section 2.* 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 XIII. Performances and expected performances may be addressed using a generic statement for each type of custom-made dental appliance 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 appliances
A prosthodontic appliance attempts to re-establish the normal function and performance of a tooth or 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 orthodontics (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 causes 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 appliances
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 due to the prescribed treatment.

Custom-made splints
The performance of a splint provides 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 an online registration form to the competent authority when all regulatory requirements are met. The competent authority will normally provide a registration acknowledgement letter and/or email containing a registration reference number. This letter or the information contained in the online register may be used to demonstrate conformity with the requirements of 4.2.3. Note that the new dental appliance manufacturers must comply with the requirements of the MDR and/or other appropriate regulations and be registered with the competent authority when they manufacture for the first time.

From 1st January 2021 dental laboratories based in Great Britain that place devices on the market in the EU or Northern Ireland should ensure that they have appointed a sole authorised representative based in the EU or Northern Ireland.

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 dental technician and require an approval signature or record of verification 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.

This list of approved materials and suppliers shall, as a minimum, be reviewed and updated annually to ensure that the list is up to date with the materials used in the laboratory.

EU and UK marking 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. All patient contact materials should comply with CE marking requirements.

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 general safety and performance requirements of the Medical Devices Regulations and, where applicable, are CE/UKCA 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 is 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.

4.4.5 Traceability

The dental appliance manufacturer shall ensure that purchased patient contact materials can be linked to an appropriate purchase order so that traceability of patient contact materials used in the manufacturer of custom-made dental appliances is maintained.

Achieving traceability can be achieved by maintaining a robust purchase order system (described in 4.4.3 and 4.4.4).

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 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 paid 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) 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 disposal 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 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 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 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 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, competency and professional registrations of personnel in relevant manufacturing and/or management system tasks, particularly personnel reviewing prescriber requirements and final inspection who must be dental technicians. 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 plants, manufacturing equipment and measuring/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.

4.8 Cleanliness

A simple documented system or procedure should be established specifying how manufacturing plants 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 MDR 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. Therefore, dental appliance manufacturers shall have in place a current infection control policy which is available from their trade association.

NOTE 2 The dental laboratory manufacturing area should be a reasonably clean environment. Cleaning procedures should be maintained to ensure the manufacturing area is free from unnecessary dirt or hazards which would contravene infection control policies.

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. This will be a fully trained and competent dental 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 final inspection checklist (Annex E) should be amended by the laboratory to correspond with the types of appliances manufactured and production processes utilised within the laboratory.

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.

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.

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 ten 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.

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; Risk Assessments; PMCF; PSUR; Internal Audit Checklists and Results of Management Reviews.

4.12 Statement

The EU and UK MDR requires the manufacturer to draw up a statement of conformity (see Section 1 of Annex XIII of the EU MDR and paragraph 1 of Section 13 UK MDR (as amended). This statement must accompany the device. It is satisfactory for a statement to be part of another document or an integral part of an invoice, label or work ticket (or any combination of these). 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 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 are either from a CE marked source or from an appropriate 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

Custom-made devices shall be accompanied by the statement referred to in Section 1 of Annex XIII of the EU MDR and Regulation 9, paragraph 5A, of the UK MDR (as amended), which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

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

- the name and address of the manufacturer, and of all manufacturing sites
- if applicable, the name and address of the authorised representative
- data allowing identification of the device in question
- a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code
- the name of the person who made out the prescription and who is authorised by national law by virtue of their professional qualifications to do so, and, where applicable, the name of the health institution concerned
- the specific characteristics of the product as indicated by the prescription
- a statement that the device in question conforms to the general safety and performance requirements set out in Annex I and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds

Example of a statement is as follows:
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 general safety and performance requirements specified in Annex I of the EU MDR and Section 13 UK MDR (as amended).

If you choose to issue a triplicate copy of the prescription as your 'patient statement', consideration should be given to the final quality of the prescription, i.e. the copy should be presentable and the information should be legible for the patient to clearly see and understand.

4.13 Labelling

Custom-made dental appliances must be labelled as specified in Chapter III of Annex I of the Medical Devices Regulations and/or Part 3 of the UK MDR (as amended). As a minimum, the following information should be on the label:

- The name or trade name of the device;
- The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;
- The name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;

- If the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;
- Date of manufacture;
- Any special storage and/or handling conditions;
- The words 'custom-made device';
- 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.

4.14.1 Post-market clinical follow-up (PMCF)

The dental laboratory should have in place a PMCF plan from which they will generate a report to include the review of complaints, remakes, feedback, product reviews and regulatory communications with the aim of implementing any necessary corrective action that has been identified and confirming the safety of the manufactured appliances.

4.14.2 Complaints and appliance nonconformity

A 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 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/report of nonconformity.
e) Define responsibility for resolving the possible complaint/report of nonconformity.
f) Decide if the possible complaint/nonconformity is justified.
g) If the possible complaint/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/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.

Information gathered from complaints recorded shall be used to produce relevant statistics for PMCF and PSUF reporting.

4.14.3 Appliance recall and reporting

Manufacturers of devices made available on the EU and UK market, other than investigational devices, shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7) of the EU MDR and the UK MDR Regulation 125(1), the following:
(a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88 (EU MDR)/Regulation 126 (UK MDR);
(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

Dental laboratories who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with these Regulations shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly. Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available.

For dental laboratories to achieve this clause a 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.

4.14.4 Periodic safety update report (PSUR)

The dental laboratory shall prepare an annual report which summarises the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan (detailed above) and the results of the annual risk assessment to confirm the safety of the manufactured appliances.
Throughout the lifetime of the device concerned, the PSUR shall set out:

- The conclusions of the benefit-risk determination;
- The main findings of the PMCF;
- The volume of sales of the device and an estimated evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

4.15 Risk management

Section 3 of Annex I of the EU MDR and Paragraph 3 of Schedule 3 of the UK MDR (as amended) introduces a requirement for the laboratory to establish, implement, document and maintain a risk management system. The purpose of running a simple risk management system is to ensure that the devices that the dental laboratory are placing on the market are safe for the patient.
Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management, manufacturers shall:
(a) establish and document a risk management plan for each device;
(b) identify and analyse the known and foreseeable hazards associated with each device;
(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;
(d) eliminate or control the risks;
(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability;
(f) based on the evaluation of the impact of the information referred to in point (e), if necessary, amend control measures.

4.16.1 Internal audits

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

- 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.

4.16.2 Management review

A simple documented system 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;
- Assessment of post-market surveillance and risk management activities;
- Performance and continuing acceptability of suppliers;
- Staff training requirements;
- Assessment of the need for action that will prevent or minimise the risk of quality problems occurring.

Annex C: Guide to the general safety and performance requirements and conformity assessment procedures

Article 5(2) of the EU Medical Devices Regulations and Regulation 5(2) of the UK MDR (as amended) states that a device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose. The requirement in this annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio. Annex I is in three parts:

Chapter/Part One – GENERAL REQUIREMENTS
The requirement of this chapter is the undertaking of a risk management system. Parts 1-8 of chapter one applies to dental appliance manufacturers.

Chapter/Part Two – REQUIREMENTS REGARDING DESIGN AND MANUFACTURE

Chapter/Part Three - REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE
Listed below are 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 general safety and performance 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 general safety and performance requirements specified in the regulations.

Section EUMDR/UKMDR	**Applicable**	**Comments**	**Section** EUMDR/UKMDR	**Applicable**	**Comments**
10.1 10.1-2	Yes		19	No	
10.2 10.3	Yes		20	No	
10.3 10.4-5	Yes		21	No	
10.4 10.6-10	No		22	No	
10.5 10.11	Yes		23.1 23.1-3	Yes	Para (a/b/c/g)
10.6 10.12	Yes		23.2 a 23.4 a	Yes	
11.1	Yes		23.2 b 23.4 b	Yes	
11.2	Yes		23.2 c 23.4 c	Yes	
11.3	No		23.2 d 23.4 d	Yes	
11.4	No		23.2 e 23.4 e	No	
11.5	No		23.2 f 23.4 f	No	
11.6	No		23.2 g 23.4 g	No	
11.7	Yes		23.2 h 23.4 h	No	
11.8	No		23.2 i 23.4 i	No	
12	No		23.2 j 23.4 j	Yes	
13	No		23.2 k 23.4 k	Yes	
14.1	Yes		23.2 l 23.4 l	No	
14.2	Yes	Para (a)	23.2 m 23.4 m	Yes	
14.3	No		23.2 n 23.4 n	No	
14.4	No		23.2 o 23.4 o	No	
14.5	No		23.2 p 23.4 p	Yes	
14.6	No		23.2 q 23.4 q	Yes	
14.7	No		23.2 r 23.4 r	No	
15	No		23.2 s 23.4 s	No	
16	No		23.3 23.5	No	
17	No		23.4 23.6	No	
18	No				

In addition, a manufacturer of custom-made medical devices must follow the procedure referred to in Annex XIII of the EU MDR and Section 13 of the UK MDR (as amended) and draw up the statement set out in that annex before placing each device on the market.

In essence, Annex XIII and section 13 requires the following:

First requirement
For custom-made devices, the manufacturer or its authorised representative shall draw up a statement containing all of the following information:

- the name and address of the manufacturer and of all manufacturing sites;
- if applicable, the name and address of the authorised representative;
- data allowing identification of the device in question;
- a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code;
- the name of the person who made out the prescription and who is authorised by national law by virtue of their professional qualifications to do so and, where applicable, the name of the health institution concerned;
- the specific characteristics of the product as indicated by the prescription;
- a statement that the device in question conforms to the general safety and performance requirements set out in Annex I and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds.

Note: Custom-made devices shall be accompanied by the statement referred to in EU MDR Annex XIII and UK MDR (as amended) section 13 which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

Second requirement
The manufacturer shall undertake to keep available for the competent national authority's documentation that indicates its manufacturing site or sites and allows an understanding to be formed of the design, manufacture and performance of the device, including the expected performance, so as to allow assessment of conformity with the requirements of this regulation.

Third requirement
The statement referred to in the first requirement shall be kept for a period of at least 10 years after the device has been placed on the market.

Fourth requirement
The manufacturer shall review and document experience gained in the post-production phase, including from PMCF, as referred to in the EU MDR Part B of Annex XIV and the UK MDR (as amended) Part B Schedule 14, and implement appropriate means to apply any necessary corrective action. In that context, it shall report in accordance with the EU MDR Article 87(1) and the UK MDR (as amended) Regulation 125(1) to the competent authorities any serious incidents or field safety corrective actions, or both, as soon as it learns of them.

Fifth requirement
A manufacturer of 'custom-made' devices must register his business with the UK Competent Authority or with the appropriate National Regulatory Authority with a description of the devices concerned and the business address.

DAMAS SPECIFICATION

Clause 4 of the DAMAS specification contains sixteen 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 4.16 have been designed to allow conformity with the "general safety and performance requirements" and "Annex XIII" of the EU MDR and Section 13 of the UK MDR (as amended) to be demonstrated to others.

The matrix below demonstrates the relationship between the MDR requirements and the sub-clauses 4.1 to 4.16 of the DAMAS specification.

MATRIX OF MEDICAL DEVICES REQUIREMENTS AND THE DAMAS SPECIFICATION																
Requirement	Met by DAMAS Specification Sub-Clause(s)															
Chapter/Part 1	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	4.16
1	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
2															x	
3															x	
4															x	
5															x	
6														x	x	
7										x				x	x	
8														x	x	
Chapter/ Part 2	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	4.16
10.1			x	x	x	x	x	x	x	x						
10.2			x	x	x	x	x	x	x	x						
10.3			x	x	x	x	x	x	x	x						
10.5			x	x	x	x	x	x	x	x						
10.6			x	x	x	x	x	x	x	x						
11.1			x	x	x	x	x	x	x	x						
11.2			x	x	x	x	x	x	x	x						
11.7										x						
14.1			x		x				x	x		x	x			
14.2			x	x	x				x							
Chapter/Part 3	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	4.16
23.1a/b/c/g												x	x			
23.2a												x	x			
23.2b												x	x			
23.2c												x	x			
23.2d												x	x			
23.2j												x	x			
23.2k												x	x			
23.2m												x	x			
23.2p												x	x			
23.2q												x	x			
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	4.16
1st Requirement												x				
2nd Requirement	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
3rd Requirement											x					
4th Requirement														x		
5th Requirement		x														

Annex D: Model Declaration 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 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, the UK Medical Devices Regulation 2002 (as amened) and the requirements of the DAMAS Management System Specification.

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

Done by: Mr A N Other

Signed:

Title: A N Other Director

Date:

Annex E: Model DAMAS Final Inspection Checklist

MUTUAL POINTS

1 Check prescription has been followed correctly.
2 Check that 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 dispatch date and time are correct.

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 dentist's 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.