

# Chairside Manufacturing FAQs



## About Us

The British Dental Industry Association provides guidance to help dental professionals understand regulatory requirements for chairside technologies such as CAD/CAM systems. Our aim is to ensure that members of the dental team understand their obligations under the regulations and how to meet them, supporting patient care and professional confidence.

### Q. Is my practice able to use chairside manufacturing technologies?

A. Yes – dental practices are able to use chairside manufacturing technologies (i.e. CAD/CAM or 3D printing) for the production of custom-made dental devices. However, this activity carries certain obligations under the Medical Devices Regulations 2002 (UK MDR).

As defined by UK MDR, a custom-made device is:

- manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other person authorised to write such a prescription by virtue of their professional qualification, which gives under their responsibility, specific characteristics as to its design
- intended for the sole use of a particular patient, but does not include a mass-produced product which comprises a medical device and medicinal product forming a single integral product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user.

## Q. What are the requirements for chairside manufacturing of dental devices?

A. If you are producing custom-made devices you are regarded as a manufacturer, and must meet the particular requirements of the UK MDR which relate to custom-made devices. These requirements include:

### Registration:

As a manufacturer of custom-made devices, you must register with the Medicines and Healthcare products Regulatory Agency (MHRA) providing information about yourself as the manufacturer and the devices you are manufacturing.

Statutory fees apply for registration.

## Labelling

As a minimum requirement the labels on a custom-made device must include:

- the name or trade name and address of the manufacturer or, for devices imported into the United Kingdom, the name and address of the [UK responsible person](#)
- the details strictly necessary for the healthcare professional to identify the device and the contents of the packaging (for example, patient name and description of device)
- the words 'custom-made device'

## Custom-made device statement

Custom-made devices, other than those classified as Class I, must be accompanied by a statement as referred to in Part II of the UK MDR 2002, Annex VIII.

It is the responsibility of the manufacturer of the device to review all the requirements of the UK MDR 2002 against their procedures. This statement must include:

- data allowing identification of the device in question: description, serial number, order number, generic name
- a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient (this may be an identification number if patient confidentiality needs to be maintained, provided it can be traced through records to the named patient)
- the name of the qualified person, medical practitioner or other authorised person who made out the prescription and, where applicable, their place of work
- the particular features of the device as specified in the relevant prescription (that is, the written prescription with its special features extracted to define the particular device)
- a statement that the device in question conforms to all the relevant essential requirements and, where it does not, the grounds for believing it is safe for use
- the name and address of the manufacturer

This statement should be made available to the named patient, and patients must be made aware that they can request a statement and the statement will need to be made available on request.

## Post-market obligations:

As a manufacturer of custom-made devices, your responsibilities do not end when the device is manufactured or when it is provided to the patient. You must continue to comply with post-market requirements under the UK MDR.

Specifically, manufacturers of custom-made devices must maintain a post-market surveillance (PMS) system for each device that is placed on the market or put into service. The manufacturer must ensure that the PMS system is used throughout the PMS period and must ensure that they use the data gathered through the PMS system to update:

- the instructions for use and labelling of the device
- design and manufacturing information
- the required risk analysis
- any evaluation of performance evaluation data confirming conformity with the relevant essential requirements
- any other technical documentation required by the conformity assessment procedures

Manufacturers must report any incidents resulting from the constituents or design of the device if they pose a serious risk to public health, or the manufacturer initiates a field safety corrective action (for example, a recall).

Ordinary return of devices to manufacturers for adjustment or fitting do not need to be reported.

### **Q. Do these requirements apply only in relation to certain manufacturing methods or processes?**

A. It is important to note that the responsibilities associated with manufacturing custom-made devices are not dependent on the processes used. If you are manufacturing custom-made devices (whether this is using a 3D printer, CAD/CAM system or traditional processes) the requirements will apply.

### **Q. Am I regarded as a manufacturer as a result of using custom-made devices made using 3D printing or CAD/CAM processes where these are produced by an external dental laboratory?**

A. No, the responsibilities associated with manufacturing custom-made devices are not dependent on the processes used and in this case the dental laboratory would be regarded as the legal manufacturer.

### **Q. Do chairside-manufactured custom-made devices need to be CE/UKCA marked?**

A. No, custom-made devices (regardless of whether they are manufactured in a dental practice using chairside manufacturing technologies or in a dental laboratory) are not required to be CE or UKCA marked.

## Helpful Links and Resources

### **Guidance: Register medical devices to place on the market**

<https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market>

### **Guidance: Custom-made devices in Great Britain**

<https://www.gov.uk/government/publications/custom-made-medical-devices/custom-made-devices-in-great-britain>

### **Guidance: Examples of statements for custom-made medical devices**

[https://assets.publishing.service.gov.uk/media/5feb6247e90e0711fa94ce3b/Examples\\_of\\_custom\\_made\\_statements\\_Dec2020.pdf](https://assets.publishing.service.gov.uk/media/5feb6247e90e0711fa94ce3b/Examples_of_custom_made_statements_Dec2020.pdf)