CED STATEMENT
UPDATE 2024

MEDICAL DEVICES REGULATION AND CHAIRSIDE CAD/CAM PROCEDURES: RIGHT OF DENTISTS NOT TO BE DEFINED AS MANUFACTURERS

Council of European Dentists
President Dr Freddie Sloth-Lisbjerg
Transparency register: 4885579968-84
Avenue de Cortenbergh 89/6
B-1000 Brussels
T +32 (0)2 736 34 29
ced@cedentists.eu
www.cedentists.eu

I. INTRODUCTION

The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 dental practitioners across Europe through 33 national dental associations and chambers in 31 European countries. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED key objectives are to promote high standards of oral healthcare and dentistry and effective patient-safety centred professional practice. With the statement below the CED wishes to clarify the role and competences of dentists using chairside CAD/CAM systems.

II. EUROPEAN REGULATORY FRAMEWORK

The Medical Devices Regulation (MDR), published on 5 May 2017 in the Official Journal of the European Union (EU), and applicable as of May 2020, "(…) *harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market (…)"*[i].

Pursuant to Article 2 of the MDR, three different actions are defined:

> *"(27) '**making available on the market'** means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;*
>
> *(28) '**placing on the market**' means the first making available of a device, other than an investigational device, on the Union market;*
>
> *(29) '**putting into service**' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;"* [ii]

The first two definitions are related to the commercial activity of supply, while the third makes reference to a different stage, i.e. the availability of the medical device to the "final user" according to its intended purpose.

The same Article 2 of the MDR defines the term "manufacturer":

> *"(30) '**manufacturer**' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, **and markets that device under its name or trademark**;"*[iii]

Therefore, to be considered a manufacturer, two requirements are needed:

a) To manufacture a device
b) To market (to make available on the market, to place on the market or to supply) that device under its name or trademark

The dental practice is 'an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.[iv]' As such, the dental practice qualifies as a 'health institution' as per the MDR Article 2(36) – '*Definitions*'. Pursuant to both Recital 30 and Article 5.4 of the MDR, manufacturing, modifying and using devices only within "health institutions", certain rules of the MDR *"should not apply since the aims of this Regulation would still be met in a proportionate manner"*[v]. Moreover, *"Devices that are manufactured and used within health institutions shall be considered as having been put into service.*[vi]*"*

III. CHAIRSIDE CAD/CAM SYSTEMS: PROCEDURES

Chairside dental CAD/CAM systems are designed to provide a complete digital workflow, starting from a digital impression, with the use of a 3D dental design software and ending with the modification of a mass-produced device (Dental ceramic-resin block) with the use of a chairside mill or 3D printer, to adapt it to the specific needs of the patient before its putting into service as part of the restoration treatment procedure.

When using a CAD/CAM system a new medical device is not actually "manufactured" or produced, but a mass-produced device (a Dental ceramic-resin block), which was already available on the market, is modified by the dentist so that it is adapted to the specific needs of individual patients. It must be highlighted that the device from the chairside CAD/CAM system use is to be considered as medical treatment, by a fully qualified dentist according to the EU Professional Qualifications Directive (2005/36/EC).

Consequently, dentists do not “market” devices, but “put them into service”, and that is so irrespective of whether it is the dentist herself/himself who manufactures the device (i.e. modifies the block to adapt it to the needs of a specific patient by using a CAD/CAM system) or if she/he orders the manufacturing of the device to a dental technician/laboratory.

It is important to note that the use of CAD/CAM system is an integrated part of the treatment process, guided, determined and followed up on by the dentist, as the leader of the dental team and as the responsible healthcare professional for the patient. It is therefore imperative to ensure that dentists maintain their undeniable right to own and use a CAD/CAM system for their patients. This right should also extend to any future developments in the CAD/CAM system, considering that it is made of different elements that can change and evolve based on eHealth and technological progress.

IV. STATEMENTS

- All devices manufactured or marketed in the Union or used to provide diagnostic or therapeutic services to persons established in the Union, **should comply with the provisions of the EU MDR.**
- **Dentists are manufacturers when they fulfil the definition of "manufacturer" in Article 2 (30) of the MDR.** The definition is fulfilled when they manufacture or fully refurbish devices and market those devices under their name or trademark.
- However, dentists are not considered manufacturers (as defined in Article 2 (30) of the MDR), **when they manufacture, modify and use devices in their clinic (health institution), provided that they comply with the provisions of Article 5.5 of the MDR**. Putting into service of the CAD/CAM devices that they manufacture should not be considered as making available on the market or placing on the market, in accordance with Article 5.4 of the MDR.

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Adopted at the CED General Meeting of November 2024

[i] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Recital 2, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

[ii] Ibid., Article 2

[iii] Ibid.

[iv] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.), Article 2, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

[v] Ibid., Recital 30

[vi] Ibid., Article 5.4