CED COUNCIL OF EUROPEAN DENTISTS

CED Statement

Dentistry and the Medical Devices Regulation (MDR)

November 2023

Council of European Dentists
President Dr Freddie Sloth-Lisbjerg
Transparency register: 4885579968-84
Numérod'entreprise: 0480.222.749
Avenue de Cortenbergh 89 /6
B-1000 Brussels
T +32 (0)2 736 34 29
ced@cedentists.eu
www.cedentists.eu

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.

The Medical Devices Regulation (MDR) 2017/745 is an essential piece of legislation for ensuring high-quality health care and a cornerstone of patient safety across Europe. Nevertheless, several years into the implementation of the MDR, there are numerous discrepancies and variations in interpretation of the role of dentists in relation to dental medical devices. This brief statement aims to outline and describe the nature of the dental practice, the dental treatment and dental medical devices as part of it.

The Council of European Dentists wishes to highlight the importance of respecting the role of dentists as, first and foremost, healthcare providers that contribute to maintaining and promoting better public health across Europe. The dental profession remains firmly committed to the implementation of the MDR and its goal of ensuring optimal patient safety across Member States. Nevertheless, through this statement, we wish to ensure that:

1) there is absolute clarity on essential definitions as to the nature of the dental practice as a health institution, committed to improving the health of citizens across Europe
2) in a Europe of overburdened and imbalanced healthcare workforce, the role of dentists in relation to dental medical devices, and their commitment to the ultimate goal of patient safety is respected and well-understood; this means providing clarity and consistency as to the role of the dentist within the MDR ecosystem and reducing any regulatory burdens that do not fulfill the MDR requirements '*in a proportionate manner*[1]'.

The nature of the dental practice: the dental practice is *'an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.*[2]*'* As such, the dental practice qualifies as a 'health institution' as per the MDR Article 2(36) – 'Definitions'. This definition is essential for the dental profession as part of the healthcare universe and must not be subject to misinterpretation or ambiguity. It is furthermore important to note that the dentist performs all activities involving the '*prevention, diagnosis and treatment of anomalies and diseases affecting the teeth, mouth, jaws and adjoining tissue*'[3].

The nature of the dental treatment: dentistry is a vast and encompassing healthcare area and as such, there is a multitude of treatments as part of the care for a patient. Nevertheless, some aspects of the dental treatment remain consistent for most cases:

---

[1] 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.), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745 : *(…) it is appropriate to provide that certain rules of this Regulation, as regards medical devices manufactured and used only within health institutions, including hospitals (…) should not apply, since the aims of this Regulation would still be met in a proportionate manner.'*

[2] 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

[3] Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, Article 36.3, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32005L0036

- As part of the treatment and care of a patient, the dentist is frequently modifying an existing device, manufacturing a device from raw materials or combining a device with another one or another type of product, which results in a new device.[4] In the majority of the cases, this process is also based on modifying a mass-produced device in order for it to be *'adapted'*[5] to reach *'the specific requirements of any professional user*.'[6] Furthermore, corresponding to the previous bullet point, '*health institutions should have the possibility of manufacturing, modifying and using devices in-hous*e'. As part of this possibility, Article 5.5 of the MDR is also in place, offering an exemption from certain obligations under the Regulation, provided that certain conditions are met.
- The device is '*used in the care or diagnosis of a patient*[7]*'* within the health institution and is '*put into service*'[8]. It is important to note that in most of the cases, once treatment is completed, the patient does not engage in any further adaptation[9] of the device (the course of the treatment and care cycle is completed 'in-house', at the health institution). Any additional steps the patient must follow (e.g. focusing on appropriate day-to-day oral hygiene and proper healing after the treatment) on their own are based on the advice, guidance and expertise of the dental practitioner.

Furthermore, the CED would like to highlight that the nature of dental treatment includes working with a number of proven, well-known medical devices that are safe and effective. As such, dental medical devices that have been on the market for years without any complaints, and are considered safe and reliable under the previous EU medical devices legislation, should be revalidated and recertified permanently and without restriction. This would further contribute to reducing the costly and bureaucratically burdensome process of recertification under the new MDR with no risk for the patient. Otherwise the legislation might lead to shortages and ultimately place patient safety and the provision of dental treatment in jeopardy.

The nature of medical responsibility: in light of their role as healthcare professionals offering diagnosis and care to a patient, dentists are committed to ensuring optimal patient safety. As such, regardless of the type of treatment and the type of medical device involved, the dentist is responsible for determining the cycle of care through diagnosis and treatment. As such, and including within the MDR stakeholder 'chain' they will always bear the professional responsibility and obligations for the health, safety and wellbeing of their patient.

Adopted at the CED General Meeting in November 2023

-ENDS-

[4] Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

[5] 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

[6] Ibid.

[7] Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

[8] Ibid., Art. 5, '*Devices that are manufactured and used within health institutions shall be considered as having been put into service.'*

[9] To explain the term 'adaptation', we use the example from the Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, under examples of devices which do not fall in the in-house definition. Those are namely cases where the devices 'can be adapted (and thus 'used') by patients themselves outside the health institution', p.7