CED COUNCIL OF EUROPEAN DENTISTS

CED Position

Implant Cards for Dental Implants

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Council of European Dentists

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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 document at hand, the CED wishes to clarify its position regarding the implant card obligation in dental implants for safeguarding patient safety. This CED position specifically applies to dental implants and not to implant materials or any other device or material intended to be placed in the teeth.

II – EUROPEAN REGULATORY FRAMEWORK

Pursuant to Article 18(3) of the Medical Devices Regulation (MDR) (EU) 2017/745 [i], published on 5 May 2017 in the Official Journal of the European Union (EU), and, as per Regulation (EU) 2020/561[ii], applicable as of 26 May 2021:

"3. *The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom*."

It has been the CED's understanding that under the MDR, all devices/materials that are affixed to the bone (such as dental implants) are not exempted from the obligation of an implant card. This would mirror the established shared interpretation of national Competent Authorities on classification of dental implants under Council Directive 93/42/EEC on Medical Devices (MDD)[iii]. The CED has no objections to this obligation. However, the CED has been recently informed of some inconsistencies [iv] in Member States' interpretations of Article 18 of the MDR.

III - IMPLANT CARD- INTENDED USE AND ENVISAGED BENEFITS

Article 18(1) of the MDR lays out the information to be provided by the manufacturer on the implant card. The implant card must clearly identify the device and provide additional relevant information[v]. Article 18(2) lays down the obligation of Member States to require health institutions or healthcare providers to deliver the implant card to the patient in question. The paragraph reads, "2. *Member States shall require health institutions to make the information referred to in paragraph 1 available, by any means that allow rapid access to that information, to any patients who have been implanted with the device, together with the implant card, which shall bear their identity*".

Additionally, in order to further clarify Article 18 of the MDR, a guidance document on implant cards[vi] has been adopted by the European Medical Device Coordination Group (MDCG). It states that the implant card is meant to help the patient identify the implanted device and to get access to information related to it. Implant cards can also be used by emergency department personnel or first responders to receive information about medical treatment or patient needs in emergency situations, this is also valid for dental emergencies.

IV - CED POSITION

The CED's mission is to promote the highest standards of oral care to ensure patient safety at all stages of dental treatment. All measures aimed at improving traceability and patient's access to relevant information about his/her health are strongly supported by the CED. At present, high standards of traceability and safety of dental implants may already be in place at the national level. Dentists should use appropriate and certified dental materials and medical devices for each patient's individualised treatment plan.

CED notices the different interpretations of the MDR and would like to stress the importance of a shared single interpretation concerning the position of implant cards.

For previous[IV] mentioned reasons CED believes that implant cards for dental implants can contribute to high standards of traceability and patients access to information.

CED considers a high standard of traceability and access to information as paramount for a best practice that promotes high standards of oral healthcare and effective patient-safety centred professional practice.

Therefore, in this context, the CED supports the view that it is best practice that a dentist who places a dental implant should supply the patient with an implant card. This recommendation supports a best practice that promotes high standards of oral healthcare, dentistry and effective patient-safety centred professional practice.

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Adopted at the CED General Meeting on 20 November 2020

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[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. The Regulation can be accessed here.

[ii] Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions. The Regulation can be accessed here.

[iii] Please also see p.70 of the Manual on borderline and classification in the community regulatory framework for medical devices. The Manual can be accessed here.

[iv] The Swedish Drug Agency decided that dental implants are exempted from the implant card obligation as they are composed of a screw and a tooth crown (which are exempted as per Article 18 MDR).

[v] Article 18(1) MDR The Regulation can be accessed here. Medical Devices: Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, pp. 3ff.

[vi] European Medical Device Coordination Group, "Medical Devices: Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices". The Guidance document can be accessed here.