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CED Statement on the implementation of the Medical Devices Regulation

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Council of European Dentists

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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.

MEDICAL DEVICES REGULATION – CED CONCERNS

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 that is applicable in all EU Member States from 26 May 2021. The MDR was initiated, among other things, with the aim of improving patient safety throughout the EU. The CED supports improvements of the system imposed by the new regulation but also expresses its deep concerns in relation to the implementation of the MDR.

As part of the implementation of the new MDR regulations, all medical devices on the market must be re-certified by May 2024 at the latest. Without this re-certification, medical devices, even if they are safe and proven medical devices, may not be placed on the market after that date.

Until today, only about 15% of these existing products have been transferred to the new system. The reason for the slow implementation is the glaring lack of Notified Bodies responsible for certification. As the certification process takes around 18 months, it is already clear that a large number of existing products may no longer be placed on the market under the current conditions from May 2024.

In addition, it should not be disregarded that there are a large number of small and medium-sized companies, especially in the dental industry, which are no longer able to cope with the massively increased requirements. An immensely increased effort due to high bureaucratic burdens and the increase of costs for certification by about three times lead to the effect that these companies renounce the further production of certain products or product groups and accordingly withdraw them from the market. According to surveys from the dental industry, at least for individual companies, up to 35% of the dental product range could be withdrawn from the market. There are therefore serious indications from the industry that the effects will not remain without consequences for the dental market.

In this respect, there is no question that from May 2024 - unless the legislator makes urgently needed corrections - the supply situation with dental medical products will be jeopardized and patients will no longer be able to receive dental care in the tried and tested form.

COBALT – CED CONCERNS

Cobalt (metal / CAS No. 7440-48-4) has been classified as a "Carcinogenic 1B, Mutagenic 2, Toxic to Reproduction 1B" substance by Delegated Regulation (EU) 2020/217 of October 4, 2019, with an entry in "Table 3: List of harmonised classification and labelling of hazardous substances" in Part 3 of Annex VI of Regulation (EC) No. 1272/2008. This classification came into force on October 1, 2021.This is based on the report of the Committee on Risk Assessment (RAC) adopted on September 22, 2017. The experts proposed the classification of cobalt as carcinogenic, category 1B, based on two inhalation carcinogenicity studies, which are available for the substance, one in rats and one in mice. Due to co-exposure to other carcinogens, epidemiological studies in humans were not considered to provide sufficient

evidence for the carcinogenicity of cobalt in humans. The experts also considered that the criteria for specification of the route of exposure were not met, and cobalt is classified as a category 1B carcinogen without specification of the route of exposure.

Dental alloy manufacturers within the Association of the German Dental Industry (VDDI) and other scientific studies have concluded that cobalt-based alloys are a valuable and currently irreplaceable treatment modality in dentistry. Furthermore, the amounts of cobalt released from these alloys are very low and therefore acceptable and harmless in relation to the tolerated daily amounts. The use of cobalt-containing alloys is today an indispensable element for dentists to provide patients with quality dental prostheses. Cobalt-based alloys have high mechanical strength and corrosion resistance and are technically irreplaceable for the specific indications mentioned above. In addition, due to their low cost, it facilitates access to dental prosthetic care for many people.

STATEMENTS

The CED therefore calls on the European Commission and competent national ministries of health to advocate for pragmatic measures to ensure the future treatment of patients in the EU with medical devices:

- The process of designation procedures of Notified Bodies must be significantly accelerated in the short term in order to significantly **increase** the number of approved **Notified Bodies**.

- For **proven existing products** that have been on the market for many years without any risks or incidents, it is necessary to adopt a pragmatic approach to the requirements for clinical data. Many of these clinical data are often not even available, and corresponding studies are often not even feasible. The high number of certificates expiring in 2023/2024 makes it impossible under the current circumstances to transfer these products completely and in time to the MDR. In this respect, **measures must be taken to keep these products on the market**. This can be achieved by extending the term of the directive certificates. For products that have been on the market for years without any complaints and are thus considered safe and reliable, the certificates should be valid permanently and without restriction, including those based on cobalt, until equivalent therapeutic alternatives (mechanical properties at similar cost) are found.

- Another possibility would be to adapt the **transition periods** specified in the MDR (Art. 120 (2) MDR), which would have to **be extended** until at least 27th May 2026. Accordingly, this would also have to be followed by an **extension of the sell-off period** under Art. 120(4) MDR until at least 27th May 2027.

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Adopted at the CED General Meeting on 18 November 2022