Updated CED Statement on the implementation of the Medical Devices Regulation

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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.

Despite measures extending the deadlines for re-certification to 2027 and 2028 (depending on the risk class of the device), and the increased capacities of Notified Bodies, issues with the MDR continue to persist and extend to the nature of implementation of the Regulation: for example, many devices under the former Medical Devices Directive (MDD) face a change in risk class under MDR, usually going into a higher class and therefore facing additional requirements. An example would be a device that used to be MDD Class I which becomes Class IIa under the MDR, leading to increased bureaucracy without actually boosting its safety aspects.Technical demands on companies and the lengthy recertification process also continue to be a reality.

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, 64% of respondents stated that the MDR requirements led to the decision to abandon/interrupt one or more product lines. There are therefore serious indications from the industry that the effects will not remain without consequences for the dental market.

The CED's overarching concern in relation to the above is that dentists simply might run out of provenly safe devices which might lead to them to having to prioritize a different type of treatment for patients – often one that requires more interventions, is more costly, requires further check-ups down the line.

STATEMENTS

In light of the ongoing consultations that may lead to the potential revision of the MDR, it is crucial that these existing problems are taken into consideration. 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:

- For **proven existing products** that have been on the market for many years without any risks or incidents (this is especially the case of a number of dental medical

devices), 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. In this respect, **measures must be taken to keep these products on the market**. 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.**

- Due to the existing problems and the lack of proven improvement in safety for patients, users and public health, the solution would be to **completely withdraw the requirement to recertify already established medical devices**;
- In general, if there are future decisions on extension periods, those need to be based on a timeframe that is '**as long as it is necessary'** rather than on a 'band-aid solution'.
- **All stakeholders across the chain need to be consulted on such solutions and provided sufficient time for providing their expertise and opinion** – e.g. while dentists do not recertify devices, they are at the end of this chain and therefore end up bearing the brunt of unexpected shortages and additional problems that other stakeholders face.

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