CED POSITION ON IMPLEMENTATION OF MEDICAL DEVICES REGULATION

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[i] is an essential piece of legislation for ensuring high-quality health care and a cornerstone of patient safety across Europe that will be applicable in all EU Member States from 26 May 2020.

The CED supports improvements of the system imposed by the new regulation but also shares two main concerns in relation to the smooth implementation of the MDR by the relevant date. These are:

- the implementation of new classification rules for all medical devices;
- the availability and capacity of Notified Bodies across the system.

Possible delays in developing both areas have caused deep concerns amongst the profession about the readiness of the system for May 2020, and the continued availability and timely accreditation of medical devices and therefore, optimal patient treatment options.

Uncertainties over the interpretation of the MDR provisions could result in shortages of medical devices currently used by health professionals on a daily basis; some devices might not be available on the market after May 2020 if their classification and/or accreditation is delayed. This would be a major issue for the provision of health services across the European Union.

In order to complete the implementation of the Regulation by May 2020, we call on the European Commission and Member States to provide detailed guidance on the classification rules, and to ensure that the necessary systems are ready and the new notification bodies appropriately staffed to take up their work by the early autumn of 2019. It is paramount to enable the start of this work as soon as possible to ensure full functionality of the new system.

The CED furthermore calls for full transparency of information on the safety of medical devices and for public access to the European Medical Devices Database (EUDAMED). Increasing the sharing of device safety information improves traceability and surveillance. In order to ensure the trust and confidence of the public in the way medical devices are regulated, all reports confirming safety should be, in so far as is practicable, publicly accessible.

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The CED will monitor the next steps in the implementation of the MDR and remains committed to working with the European Commission through its involvement in the Medical Devices Coordination Group, and to providing other support where needed.

Unanimously adopted by the CED General Meeting on 24 May 2019

[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/EE.