COUNCIL OF EUROPEAN DENTISTS

MAY 2011

// CED RESOLUTION

CED POSITION ON THE REVISION OF THE EU REGULATORY FRAMEWORK FOR MEDICAL DEVICES

COUNCIL OF EUROPEAN DENTISTS (formerly EU Dental Liaison Committee)
President Dr Wolfgang Doneus
T +32 (0)2 736 34 29 F +32 (0)2 740 20 26 ced@eudental.eu www.eudental.eu

// INTRODUCTION

The Council of European Dentists (CED) is the representative organisation for the dental profession in the EU, representing over 320,000 practising dentists through 32 national dental associations. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED promotes high standards of oral healthcare and effective patient-safety centred and evidenced-based professional practice across Europe.

// REVISION OF THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES

The CED is aware of the intention of the European Commission to present in 2012 a formal proposal for a fundamental revision of the Medical Devices Directives (Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EEC). We attach great importance to this initiative.

The CED has participated in the 2009-2010 Exploratory process on the future of the medical devices sector and in the 2011 High level conference Exploring innovative healthcare – The role of medical technology innovation and regulation. We look forward to further contributing to the revision process, including through our participation in the Medical Device Expert Group (MDEG).

The CED supports the revision of the EU regulatory framework for medical devices and believes that the changes should be aimed particularly at increasing safety of patients and quality of medical devices available in the EU market. CED members are especially concerned about the potential dangers of outsourcing of medical devices, specifically dental prostheses, often to low wage countries, and believe that appropriate safeguards should be introduced to ensure safety and quality of these medical devices.

The present document sets out general CED policy in connection to the revision of the Medical Devices Directives. Our proposals will be elaborated as the revision process progresses.

// DEFINITIONS

The CED supports clarifying the definitions of “custom-made devices”, “manufacturer”, “placing on the market”, “putting into service” and “authorised representative”, particularly as they relate to dental prostheses (Article 1 of Directive 93/42/EEC). The current definitions allow importers to make minor adjustments to the medical devices produced outside the EU, to declare themselves as manufacturers and to market the devices as being produced in the EU, resulting in misinformation to the users of medical devices and to the patients.

// STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

The CED asks for strengthening the requirements for provision of information to the patients and to the end users of medical devices on the origin of medical devices, particularly dental prostheses. This could be achieved by amending Annex VIII of Directive 93/42/EEC (Statement concerning devices for special purposes) as follows:

- Amend point 1 of the Annex VIII to read: For custom made devices or for devices intended for clinical investigations the manufacturer or his authorized representative must draw up and submit to the end users the statement containing the information stipulated in Section 2 together with the device.

- Include in the list of information that the manufacturer or his authorized representative must draw up for custom-made devices “in case of outsourcing beyond the European Union, the name and address of all manufacturing site(s) of the medical device, including all sites of total or partial subcontracting” (point 2.1. of Annex VIII) and
- Amend point 3. of Annex VIII to read: “The manufacturer must also undertake to keep available for the competent national authorities and submit to the end users:”.

// UNIQUE DEVICE IDENTIFICATION

The CED supports in principle the intention of the European Commission to enhance transparency and traceability of medical devices on the EU market. One of the policy options considered in connection to this objective is the implementation of an EU-wide Unique Device Identification (UDI) system.

The CED notes that any initiatives such as the UDI should be carefully evaluated as they may not be appropriate to all kinds of medical devices and to all healthcare contexts. Specifically, the CED does not believe that UDI would improve traceability of custom-made devices which are already linked to a specific patient. In addition, UDI could lead to disproportionate costs for end users in primary care, individual and small practices, the environment in which the majority of European dentists work. The CED therefore recommends considering exemptions to the possible UDI requirement.

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Adopted unanimously by the CED General Meeting on 27 May 2011