EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

Brussels, 12 SEP. 2017
GROW/D4/MK/az
grow.ddg1.d.4(2017)4371362

Mr. Laurent Munerot – President
Mr. Pierre Zammit – Secretary General
European Federation of Laboratory Owners and Independent Dental Technicians (FEPPD)
e-mail: office@feppd.eu

Dear Mr. Munerot, dear Mr. Zammit,

Thank you for your e-mail of 10 July registered under Ares(2017)3568001.

The categorisation of a product in relation to Community law and the application of Community law are tasks of the national authorities, which have to carry out an analysis on a case by case basis. Please refer to the competent authorities of your members places of business. However, on the basis of the provided information, we can provide the following preliminary guidance as first answers to your questions:

Are both dentists and/or dental technicians who produce crowns or inlays by using CAD/CAM systems covered by the definition of 'manufacturer' within the Medical Device Regulation (MDR)? If not, why would a dentist and/or dental technician be excluded from the scope of the Medical Device Regulation?

Dentists and dental technicians are manufacturers when they fulfil the definition of "manufacturer" in Article 2(30)[1]. Read in conjunction with Article 5(1) and Article 2(27)(28)(29), the expression "markets that device" must be understood as encompassing both the "placing on the market" of devices and/or "the putting into service" of devices not previously placed on the market. Otherwise, economic operators only putting devices into service (such as gas installations or devices used in the context of online services) would be exempted from the MDR which is not compatible with the explicit wish of the legislator expressed in Article 6(2).

A dental technician working on request of the dentist places the crown or inlay on the market because he supplies (for the first time) a device for use by the dentist (Article 2(27)(28)). Dentists producing crowns or inlays for their patients might be regarded as placing medical devices on the market in so far as they supply them for consumption. But even if they were not placing them on the market, they would at least put them into service by affixing them in the mouth of the patient. The fact that the dentists are also "users" does not seem to change anything to this analysis, and this for the same reason as set-out at the end of the last paragraph.

---

1 All references to Articles are meant to refer to Regulation (EU) 2017/745.

The fact that dentists do so in the context of a service provided to the patient does not change anything with regard to EU medical devices law which is not subject to any limitations, definitions or interpretations set-up by national professional law. There is no exemption foreseen in the EU medical devices law for devices put into service by dentists in the framework of their service. On the contrary: many medical devices are just put into service in the context of service providing, and still the legislator wished to cover these situations as "putting into service", as one can clearly see in Article 6(2).

Accordingly, we currently see no reason to regard a dentist or dental technician as being excluded from the scope of the Medical Device Regulation.

Do crowns or inlays produced by CAD/CAM systems fall within the scope of the Medical Device Regulation?

Crowns or inlays fall within the scope of the MDR if they are deemed by their manufacturers to have a medical purpose in the meaning of the definition of medical device contained in Article 2(1) of the MDR.

If so, do they fall under the definition of a custom-made device?

Again, the method of manufacturing is not decisive for the qualification as custom-made device. To be a custom-made device, a device must fall under the definition of Article 2(3) MDR.

Or are crowns or inlays produced by CAD/CAM systems excluded from the definition of a custom-made device, since the blocks from which they are manufactured are "mass-produced devices which need to be adapted to meet the specific requirements of any professional user"?

"Mass-produced devices which need to be adapted to meet the specific requirements of any professional user" are devices which as such can already be used for medical purposes, but still need to be adapted to the patient in question following specific requirements of a professional user. This is not the case with raw material blocks. The blocks as such cannot be used as medical device. We would regard them rather as raw material for the manufacturing of a medical device.

Yours sincerely,

Manfred Kohler
Legal Officer