Bundesverband der implantologisch tätigen Zahnärzte in Europa

European Association of Dental Implantologists

European Medical Device Regulation MDR

Person responsible for regulatory compliance (PRRC)

according to Article 15 MDR and IVDR (In-vitro Diagnostic Device Regulation)

PRRC responsible to meet requirements for the dental practice and the dental lab[1]

Name and address of the dental practice/dental lab

Authorized representatives:

Authorised representatives shall have **permanently and continuously at their disposal** at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications

☐ a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline,
and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

☐ four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Roles and responsibilities of the person responsible for regulatory compliance within a manufacturer (paragraph 3)

- *the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;*
- *the technical documentation and the EU declaration of conformity are drawn*
- *up and kept up-to-date;"*
- *the post-market surveillance obligations are complied with in accordance with Article 10(10) [Article 10(9) of the IVDR];*
- *the reporting obligations referred to in Articles 87 to 91 [Article 82 and 86 of the IVDR] are fulfilled;*
- *in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV [Section 4.1 of Annex XIV of the IVDR] is issued.*

Person responsible

Owner of Practice/Lab

Date and signature

Date and signature

[1] "Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal."