Person Responsible for Regulatory Compliance – The ''Art. 15 man''

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Art. 15

- EU-MDR 2017/745 mandates that MedTech companies have a regulatory expert, who will be ensuring that the company conforms with the certain requirements.
- Manufacturers and Authorized Representatives (ARs) are mandated to have at least on PRRC
- Also refer to MDCG 2019-7 for further guidance

15 (3)

Responsibilities

- 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)
- the reporting obligations referred to in Articles 87 to 91 are fulfilled
- in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued

15 (1) Profile – 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 (4) years of professional experience in regulatory affairs or in quality management systems relating to medical devices

** manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing

15 (5)

The person responsible for regulatory compliance **shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties**, regardless of whether or not they are employees of the organisation

15 (4)

If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1, 2 and 3, their respective areas of responsibility shall be stipulated in writing.

15 (2)

Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC (36) 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.

PRRC and Authorized Representative (AR)

- When the manufacturer is headquartered outside of the EU and an Authorized Representative (AR) is required, the PRRC performs additional controls in order to confirm regulatory compliance
- The PRRC of an AR should be responsible for ensuring that the tasks of an AR in accordance with Article 11(3) are fulfilled

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- You can have more than one PRRC with different roles and responsibilities that must be defined in written
- Name and contact details of the PRRC will be disclosed in the EUDAMED database
- The role is mandatory in the IVDR context as well