

Appointment as Person Responsible for Regulatory Compliance

Effective from *DATE*, the management (top management) of *COMPANY NAME* appoints

PRRC name (company name, if external)

as its Person Responsible for Regulatory Compliance (PRRC) according to article 15 of the EU Medical Device Regulation (EU) 2017/745 (MDR). *COMPANY NAME* acts as a manufacturer of medical devices within the scope of the aforementioned EU Regulation.

The PRRC has to ensure that:

1. 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;
2. the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;
3. the post-market surveillance obligations are complied with in accordance with Article 10(10) of the regulation;
4. the reporting obligations referred to in Articles 87 to 91 (MDR) are fulfilled;
5. in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV (MDR) is issued.

The company gives the PRRC the necessary authority and responsibility to perform the tasks and provides the appropriate resources.

The PRRC ensures permanent and continuous availability in accordance with the contractual agreement.

Place, Date

Management Representative // Person Responsible for Regulatory Compliance

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