**[Letterhead of declaring manufacturer]**

**Legal entities….**

**LETTER OF APPOINTMENT  
"Person responsible for regulatory compliance acc. to Article 15 MDR”**

We herewith appoint *[title, first and last name]*, *[function]*, employee of *[company of manufacturer]* as

**Person responsible for regulatory compliance (PRRC)**

according to Article 15 REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (**MDR**),

**for the *[company of manufacturer]*.**

*[Name of PRRC]* bears the title of *[new function]*, her/his office is located at *[address].*

The PRRC’s duties and responsibilities are defined in **Annex 1**.

*[Name of PRRC]* hereby confirms as new PRRC

* that she/he accepts the office and duties of the PRRC for the *[company of manufacturer]* as defined above and
* that she/he fulfills the necessary qualifications according to Article 15 para 1 of MDR, which are described in detail in **Annex 2**.

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Place, Date |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Place, Date |
| ***[declaring manufacturer/legal entity]*** |  | ***[Title and full name of PRRC]*** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *Signature of director or duly authorized representative* |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *Signature of PRRC* |

**Annex 1**

**List of duties and responsibilities of the PRRC**

**The following duties and responsibilities refer to the following listed medical devices of *[manufacturer]*:**

* […]
* […]
* […]

**Duties and Responsibilities according to Art. 15 para 3 MDR**

* 1. Art. 15 para 3 (a): appropriate check of the conformity of the aforementioned devices in accordance with the quality management system under which such devices are manufactured and before such device is released
  2. Art. 15 para 3 (b): drawing up and keeping up to date of the technical documentation and the EU declaration of conformity of aforementioned devices
  3. Art. 15 para 3 (c): fulfillment of the post-market surveillance obligations in accordance with Article 10(10)
  4. Art. 15 para 3 (d): fulfillment of reporting obligations referred to in Articles 87 to 91
  5. Art. 15 para 3 (e): in the case of investigational devices, issuance of the statement referred to in Section 4.1 of Chapter II of Annex XV

The PCCR will fulfill the aforementioned duties and responsibilities in compliance with all legal and regulatory requirements and in compliance with the company´s Standard Operating Procedures (SOPs) hereto.

**Annex 2**

**List of formal qualifications of PRRC acc. to Art. 15 para 1 MDR**

|  |  |  |  |
| --- | --- | --- | --- |
| **Evidence acc. to Art. 15 para 1 s. 1 (a)** | | | |
|  | **Discipline / name and date of degree**  **/**  **Description of professional experience, function/job title** | **university/ college, period of studies**  **/**  **Employer’s company, period of employment** | **Original certificate or certified copy supplied as evidence**  **(yes/no)** |
| (1) 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; |  |  |  |
| (2) and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices |  |  |  |
| *Further formal qualifications which evidence PRRC’s requisite expertise in the field of medical devices* |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Evidence acc. to Art. 15 para 1 s. 1 (b)** | | | |
|  | **Description of professional experience, function/job title** | **Employer’s company, period of employment** | **Original certificate or certified copy supplied as evidence**  **(yes/no)** |
| four years of professional experience in regulatory affairs or in quality management systems relating to medical devices. |  |  |  |
| *Further formal qualifications which evidence PRRC’s requisite expertise in the field of medical devices* |  |  |  |