**Intended purpose, qualification, classification, and selection conformity assessment procedure**

1. **Manufacturer Information**

|  |  |
| --- | --- |
| **Manufacturer** |  |
| **SRN** |  |
| **Responsible Person** |  |

1. **Description and Specification of the Medical Device**

|  |  |
| --- | --- |
| **Medical Device (Trade Name)** |  |
| **Basic UDI-DI** |  |
| **UDI (UDI-DI + UDI-PI)** |  |
| **CND Code(s)** |  |
| **General Description** |  |
| **Accessories** |  |

1. **Legal basis for the placing of the product on the market**

This product is placed on the European market based on the following legal requirements:

Regulation (EU) 2017/745 on medical devices

Regulation (EU) 2017/746 on in vitro diagnostic medical devices

1. **Intended purpose**
2. **Contraindications**

The following contraindications are known for the software "Name":

*Not applicable or naming contraindications*

1. **Qualification of software as medical device**

The software "Name" is a medical device according to Art. 2 (1) MDR and MDCG 2019-11.

Rationale:

1. **Classification of software as medical device**

According to Art. 2 (1) MDR and MDCG 2019-11, the software "name" is assigned to the following risk class:

I  Im  Is  IIa  IIb  III

Rationale:

1. **Selection of conformity assessment procedure**

Based on the risk classification, the following conformity assessment procedure is selected for the software "Name": *e.g., according to Annex XI Section 10 as well as the technical documentation (Annex II and III) of the EU Regulation 2017/745 according to Art. 52 MDR*

I confirm the correctness of the information given above.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place, date Title, first name, last name

Function

Organization