**EU declaration of conformity**

**Manufacturer information:**

**Name: \*\*\*\***

**Address: \*\*\*\***

**SRN:** **\*\*\*\***

**Authorised representative information:**

**Name:** **\*\*\*\***

**Address: \*\*\*\***

**SRN:** **\*\*\*\***

**Product covered by the EU declaration of conformity:**

**Product and trade name****:** **\*\*\*\***

**Model: \*\*\*\***

**Basic UDI-DI: \*\*\*\***

**Risk class:** Class IIa (according to ANNEX VIII of REGULATION (EU) 2017/745)

**CS:** Not applicable

**Notified body: \*\*\*\***

**CE certificate No.: \*\*\*\***

**Conformity Assessment Procedure:** Chapters I and III of Annex IX

**We herewith declare that the device is covered by the present declaration is in conformity with REGULATION (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices and the EU declaration of conformity is issued under the sole responsibility of the manufacturer. All supporting documentations are retained under the premises of the manufacturer.**

**Name(printed): \*\*\*\*\*\*\*\* Function or Title: \*\*\*\*\*\***

**Signature:**

**Place:**  **Date (YYYY-MM-DD）:**

**Issue on behalf of *{公司名称}*.**