Manufacturer's Logo

EU Declaration of Conformity

Product Identification:

Product Name:
Other Name:
Model Number/ Catalogue Number:
Basic UDI- DI:
Intended Purpose:
Product Code:

Manufacturer:

Name of the company:
Address:
Telephone:
Single Registration Number (SRN):

Authorised Representative:

Name of the company:
Address:
Telephone:
Single Registration Number (SRN):

Registration Information:

Notified Body Name:
Notified Body Number:

Insert CE Mark

CE cccc

Conformity Assessment:

Device Classification:
Route to Compliance: Medical Device Regulation (MDR) (EU) 2017/745 and based on Rule XX; Annex VIII, classification criteria.

Manufacturer's Logo

Registered name of the Manufacturer hereby declares under our exclusive responsibility the above-mentioned products meet the provisions of the European Regulation (EU) 2017/745 for Medical Devices and those General Safety and Performance Requirements listed in Annex I and the conformity Assessment requirements of Annex IX as well as any applicable standards, any common specifications, or related European Union legislation.

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Representative Name **Title**

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Signature **Date** **Place of Issue**