EC Declaration of Conformity

Manufacturer Name: _____
Manufacturer address: _____

SRN (single registration number): _____

Basic UDI-DI: _____
Name of the device: _____
Product code: _____

Classification: Class 1

Conformity assessment route:
_____(*Name Manufacturer*) uses the following procedures
for CE-labelling for their products according the regulation MDR 2017/745:

Class 1: EC conformity declaration according to Annex II + Annex III.

This declaration is issued under the sole responsibility of _____
We hereby declare that the medical device specified above meet the provision of the regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer and is designed and produced in accordance with (EU) Medical Device Regulation 2017/745.

Place and date of issue: _____, _____

Issued by: _____ Signature: