# Declaration of Conformity

# For

# [Device Name]/OR Devices under EU Certificate XXXX

# Manufacturer identification

|  |  |
| --- | --- |
| Legal Manufacturer | [Manufacturer Name] |
| Address of registered place of business |  |
| SRN |  |

# Authorized representative details

*Non-applicable for manufacturer located in EU.*

|  |  |
| --- | --- |
| Authorized representative name |  |
| Address |  |
| SRN |  |

# Liability

We, [Manufacturer Name], company located at [address], declare that the present EU Declaration of Conformity is issued under our sole responsibility.

# Basic UDI-DI

|  |  |
| --- | --- |
| Basic UDI-DI |  |

# Product identification

*Annex IV section 4 also list “photograph” [of the device] as a possibility, if you wish, you can add a column in the table below.*

|  |  |  |
| --- | --- | --- |
| **Product name / Trade name** | **Product Code / Catalog N°** | **Intended use** |
|  |  |  |
|  |  |  |

# Device classification

|  |  |
| --- | --- |
| Risk class  |  |
| Rule |  |

# Statement

We, [Manufacturer Name], company located at [address], declare under our sole responsibility that the device covered by the present declaration:

* Has been manufactured under consideration of European Regulation (EU) 2017/745 or (EU) 2017/746
* Has been assesses according to European Regulation (EU) 2017/745 or (EU) 2017/746 Annex IV – EU Declaration of conformity
* Has been classified according to European Regulation (EU) 2017/745 or (EU) 2017/746 Annex VIII – Classification rules
* complies with all applicable requirements of European Regulation (EU) 2017/745 or (EU) 2017/746 Annex I – General Safety and Performance Requirements.

[Manufacturer Name] established and maintains a quality management system for compliance with the requirement of EN ISO 13485:2016 and EN ISO 13485:2016/AC: 2018.

# References to CS

Non-applicable.

Or

|  |  |
| --- | --- |
| Common specifications |  |
|  |

# Notified Body information

*Non-applicable for Class I under MDR or Class A under IVDR self-certified devices*

|  |  |
| --- | --- |
| NB name |  |
| NB address |  |
| NB identification number |  |
| Conformity assessment procedure  | (EU) 2017/745, Annex: XXX or (EU) 2017/746, Annex: XXX*Indicate the conformity assessment procedure of the MDR/IVDR EU certificate e.g., Annex IX/X/XI.* |
| Certificate number | XXX |

# Additional information

None

# Signature

|  |  |
| --- | --- |
| Place |  |
| Effective date  |  |
| Name  |  |
| Function  | PRRC |
| For, and on behalf of whom  |  |
| Signature |  |