**Declaration of Conformity**

For

[Device Name]

/OR Devices under EU Certificate XXXX

Manufacturer Name: [Manufacturer name]

Document Number: XXXX

Revision: XXXX

# Manufacturer details

|  |  |
| --- | --- |
| **Manufacturer name:** | [Manufacturer name] |
| **Address:** |  |
| **SRN:** |  |

# Authorized representative details

*Non-applicable for manufacturer located in EU.*

|  |  |
| --- | --- |
| **Authorized representative name:** |  |
| **Address:** |  |
| **SRN:** |  |

# Notified bodies details

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

|  |  |
| --- | --- |
| **Notified body name:** |  |
| **Notified body identification number:** |  |
| **EU Certificate:** |  |
| **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.* |

# Device details

|  |  |
| --- | --- |
| **Device trade name(s):** | [Device name] |

Further information is in Annex I – Device details.

# Declaration

[Manufacturer name] declares:

* the EU declaration of conformity is issued under the sole responsibility of [Manufacturer name].
* the devices described in Annex I that are covered by the present declaration is in conformity with (EU) 2017/745 or (EU) 2017/746
* *To be removed if not applicable* the devices described in Annex I that are covered by the present declaration is in conformity with the following other relevant Union legislations requiring an EU declaration of conformity:
  + XXX

# References

No common specifications are applicable to [device name].

*/or*

The following table describes the common specifications applicable to [device name].

|  |  |
| --- | --- |
| **Common specifications:** | XXX |
| XXX |

# Approval

Place of issue of the self-declaration: Address, Country

Date: DD Month YYYY

Approver name: John Doe

Function: PRRC

Signature:

# Annex I – Device details

| **Basic UDI-DI** | **Device trade names** | **UDI-DI** | **Risk class and rule per Annex VIII** | **Intended purpose** | **Picture** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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