**Template Instructions:**

1. Place the content of this document on your company letterhead
2. Items highlighted in yellow should be reviewed and replaced with your information
3. Remove the highlights

**DECLARATION OF CONFORMITY**

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Manufacturer declares, under its sole responsibility, that the product(s) covered in this document are in conformance with the requirements of the In Vitro Diagnostic medical device Regulation (EU) 2017/746 and list other EU legislation/Directives as applicable (or delete the highlighted section if not applicable).

|  |  |
| --- | --- |
| **Manufacturer Name** |  |
| **Manufacturer Address** |  |
| **Manufacturer SRN** | Note: The Single Registration Number (SRN) uniquely identifies every economic operator (authorized representative, system/procedure pack producer, manufacturer, importer) in EUDAMED and is required in the DoC once issued. EUDAMED is currently voluntary and is expected to be fully functional by Q2 2024 Delete row if SRN not yet issued. |
| **EU Authorized Representative** | Note: Include name, address, phone, email and SRN of Manufacturer’s EU AR, if applicable.    Name  Address  Tel:  Email:  SRN: |
| **Product Name** |  |
| **Product Catalogue Number(s) / Code(s)** | Note: The product code, catalogue number, photograph or other unambiguous reference allowing identification and traceability of the device is optional if the Basic UDI-DI is provided. Delete this row if you opt not to list the numbers/codes. |
| **Basic UDI-DI** | Note: Basic UDI-DIs are specific to Europe and mandatory in the MDR DoC. They are essentially the 'parent' UDI-DI to a group of UDI-DIs all contained within a single product family and must be issued by your UDI issuing agency. |
| **Intended Use** | Note: May be excluded from DoC if the intended purpose is adequately included in the Basic UDI-DI.  Delete this row if your Basic UDI-DI adequately provides the intended use and you opt not to add it to this DoC. |
| **Classification** | Class XX, Rule XX |
| **Common Specifications / Standards Applied** | Note: ‘common specifications’ (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.  If any common specifications are applicable to your device type, it is mandatory to comply and list them here. Standards are voluntary, and optional to list on the DoC. |
| **Notified Body Name & ID #** |  |
| **Conformity Assessment Route** |  |
| **CE Certificate Number** |  |
|  | |
| **Name** | Note: Document should be signed by a senior level management member representing the company |
| **Title** |  |
| **Signature** |  |
| **Place of Issuance** |  |
| **Date** | DD/MM/YYYY |