**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**

Manufacturer declares, under its sole responsibility, that the product(s) covered in this document are in conformance with the requirements of Council Directive 93/42/EEC for Medical Devices and its transposition into the national laws of the Member States.

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| --- | --- | --- |
| **Manufacturer Name** | |  |
| **Manufacturer Address** | |  |
| **EU Authorized Representative** | | Note: Include name, address, phone and email of Manufacturer’s EU AR. EEA member state manufacturers may not require an EU AR and can delete this row.  Name  Address  Tel:  Email: |
| **Product Name** | |  |
| **Product Model Number** | | Note: The device must be "clearly identified by means of product name, product code or other unambiguous reference”. If too many to list in this section, then state: See Attached Appendix, and add list of products as an Appendix. |
| **Classification** | | Class XX, Rule XX |
| **Conformity Assessment Route** | | Annex XX of Council Directive 93/42/EEC |
| **Standards Applied** | | Note: This section is optional – if manufacturer chooses not to include standards, delete this row |
| **Notified Body Name and ID #** | |  |
| **CE Certificate Number** | |  |
|  | | |
| **Name** | Note: Document should be signed by a senior level management member representing the company | |
| **Title** |  | |
| **Signature** |  | |
| **Date** | DD/MM/YYYY | |