**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 98/79/EC for In Vitro Diagnostic Medical Devices and its transposition into the national laws of the Member States.

|  |  |
| --- | --- |
| **Manufacturer Name** |  |
| **Manufacturer Address** |  |
| **EU Authorized Representative** | Note: Include name, address, phone and email of Manufacturer’s EU AR.    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** | Self-Certified |
| **Conformity Assessment Route** | Annex III of Council Directive 98/79/EC |
| **Standards Applied** | Note: This section is optional – if manufacturer chooses not to include specifications, delete this row |
|  | | |
| **Name** | Note: Document should be signed by a senior level management member representing the company | |
| **Title** |  | |
| **Signature** |  | |
| **Date** | DD/MM/YYYY | |