**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 **Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).**

|  |  |
| --- | --- |
| **Manufacturer Name** |  |
| **Manufacturer Address** |  |
| **UK Responsible Person** | Note: Include name, address, phone and email of Manufacturer’s UK Responsible Person, if applicable.  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** | Delete non-applicable classifications:  General IVD, self-certified  IVD for Self-testing  Annex II, List A  Annex II, List B |
| **Conformity Assessment Route** | Available UKCA conformity assessment routes for higher-risk IVDs may vary and are outlined in [this MHRA guidance](https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ukca-mark#assessment-routes)  The route for General self-certified IVDs is:  Part IV of the UK MDR 2002, Annex III Sections 1-5 (as modified by Part III of Schedule 2A to the UK MDR 2002) |
| **UK Approved Body Name and ID #** | Delete this row for ‘General IVD, self-certified’ IVDs  Name:  Identification Number: |
| **UKCA Certificate Number** | Delete this row for ‘General IVD, self-certified’ IVDs  Certificate Number:  Certificate Issue Date: |
| **Standards Applied** | Note: This section is optional – if manufacturer chooses not to include standards, delete this row |
|  | |
| **Name** | Note: Document should be signed by a senior level management member representing the company |
| **Title** |  |
| **Signature** |  |
| **Date** | DD/MM/YYYY |