**Manufacturer’ details**

|  |  |
| --- | --- |
| **Manufacturer’s name** |  |
| **Address** |  |
| **Contact Name** |  |
| **Contact Phone number** |  |
| **Contact e-mail** |  |

**Product Details**

|  |  |
| --- | --- |
| **Product family Name** |  |
| **Product Description** |  |
| **GMDN #** |  |
| **NSAI CE Certificate Number:** | e.g. 252.XXX/253.XXX/745.XXX |

**Models/ sizes affected**

|  |  |  |
| --- | --- | --- |
| **Product Code** | **Description *(including size if applicably)*** | **UDI Identifier** |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **MIR Number / Unique Identifier** |  |
| **Competent Authority Reference Number** |  |
| **Relevant Competent Authority:** |  |
| **Date Company was made aware of the incident** | DD-MMM-YYYY |
| **Date Company filed initial vigilance report** | DD-MMM-YYYY |
| **Did Incident result in a field safety corrective action (FSCA)** |  |
| **Did incident result in a field safety notice (FSN)** |  |
| **Final CA Report date** | DD-MMM-YYYY |

|  |  |
| --- | --- |
| **Company Signature and Date:** |  |

**After Completion:**

Forward a **completed version of this form** and a copy of the associated **Manufacturers Incident Report** to**:** **vigilance@nsai.ie**

The Manufacturer Incident Report form is located on the EU Website.

The current version can be searched for here: https://ec.europa.eu/docsroom/