**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 #** |  |

**Models/ sizes affected**

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

|  |  |
| --- | --- |
| **Vigilance report Number / Unique identifier** |  |
| **Competent Authority reference number** |  |
| **Vigilance report filed with the following Competent Authority** |  |
| **Date Company was made aware of the incident** |  |
| **Date Company filed initial Vigilance report** |  |
| **Did incident result in a Field Safety Corrective Action (FSCA)** |  |
| **Did incident result in a Field Safety Notice (FSN)** |  |
| **Final CA report date** |  |

|  |  |  |
| --- | --- | --- |
|  |  | **Date:** |
| **Company Representative signature** |  |  |

1. Attach copy of Vigilance Report

2. Forward completed form electronically to**:** [**vigilance@nsai.ie**](mailto:vigilance@nsai.ie)