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**Appendix 1 – Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)**

(According to the European Union Medical Device Vigilance System, version 7.2.1)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Section 1: Administrative information** | | | | | | | | |
| **1.1** | **Corresponding Competent Authority** | | | | | | | |
| **a** | [Name of receiving Competent Authority] | | | | | | | |
| **b** | [EUDAMED number of NCA] | | | | | | | |
| **c** | … | | | | | | | |
| **d** | … | | | | | | | |
| **1.2** | **…** | | | | | | | |
| **a** | … | **b** | … | | | | **c** | … |
| **d** | … | | | | | | | |
| **e** | … | | | | | | | |
| **f** | … | | | | | | | |
| **1.3** | **…** | | | | | | | |
| **1.3.1** | **…** | | | | | | | |
| **a** | … | | | | | | | |
| **b** | … | | | | | | | |
| **c** | … | | | | | | | |
| NCA’s local reference number | | | … | | | | |
| EUDAMED’s reference number | | | … | | | | |
| Manufacturer’s reference number | | | … | | | | |
| **d** | … | | | | | | | |
| NCA’s local FSCA reference number | | | … | | | | |
| EUDAMED’s FSCA reference number | | | … | | | | |
| … | | |  | | | | |
| **e** | … | | |  | | | | |
| **f** | ... | | |  | | | | |
| **1.3.2** | **Manufacturer information** | | | | | | | |
| **a** | [Organization name] | | | | | | | |
| **b** | … | | | | | | | |
| **c** |  | | | |  |  | | |
| **e** |  | | | |  |  | | |
| **g** |  | | | | | | | |
| **h** |  | | | |  |  | | |
| **j** |  | | | |  |  | | |
| **l** |  | | | |  |  | | |
| **1.3.3** | **Authorized representative information** | | | | | | | |
| **a** | … | | | | | | | |
| **b** | … | | | | | | | |
| **c** | … | | | |  |  | | |
| **e** |  | | | |  |  | | |
| **g** |  | | | | | | | |
| **h** |  | | | |  |  | | |
| **j** |  | | | |  |  | | |
| **l** |  | | | |  |  | | |
| **1.3.4** | **Submitter’s details, if other than manufacturer or authorized representative** | | | | | | | |
| **a** | [Registered commercial name of company] | | | | | | | |
| **b** | [Contact first name] | | | | **c** | [Contact last name] | | |
| **d** | [E-mail] | | | | **e** | [Phone number] | | |
| **…** | … | | | | | | | |
| **…** | … | | | | **…** | … | | |
| **…** | … | | | | **…** | … | | |
|  | … | | | | **…** | … | | |

…

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