

**Medical Devices**

**Post Market Surveillance Application Form**

**Submission Details**

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| **Directive** | **NSAI file number** |
| MDD (93/42/EEC) | 252. |
| AIMD (90/385/EEC) | 253. |

This NSAI post market surveillance form is drafted as per the recommendations of the guidance document MEDDEV 2.12/2 Rev 2 (Jan 2012) – Guidelines on post market clinical follow-up studies.

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| **Product name:** | |  |
| **Manufacturer:** | |  |
| **Classification of Medical Device:** | |  |
| **Date CE Mark was granted:** | |  |
| **Date device was commercialised:** | |  |
| **Conditions of approval:** | | |
| 1. |  | |
| 2. |  | |
| 3. |  | |

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| --- | --- |
| Legal Manufacturer’s Name |  |
| Legal Manufacturer’s Address |  |

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| **TABLE 1** | |  |  |  |
|  | **Report date** | **Reviewed by** | **Date of review** |  |
| Post market surveillance report #1 |  |  |  |  |
| Post market surveillance report #2 |  |  |  |  |
| Post market surveillance report #3 |  |  |  |  |
| Post market surveillance report #4 |  |  |  |  |
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| **TABLE 2 POST MARKET SURVEILLANCE REPORT** | |
| Date product went on the market |  |
| Number of units sold |  |
| Number of Complaints |  |
| Complaint rate |  |
| Have there been any trends identified in relation to complaints |  |
| Number of adverse events EU |  |
| Number of adverse events Rest of World |  |
| Were there any unforeseen risks |  |
| Number of Vigilance reports to Competent Authority |  |
| Vigilance report rate |  |
| Number of World wide reportable incidents |  |
| Number of product recalls EU |  |
| Number of product recalls World wide |  |
| Were there any Corrective actions arising from complaints or adverse events |  |
| What is the status of the Corrective Action |  |
| Who authored the Post market surveillance report |  |
| Did a clinical expert review this PMS |  |
| Please provide bio /CV of author |  |
| Please provide bio/CV of clinical expert |  |
| In the case of CAPA’S or recalls please give details below: | |
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| **Section 1: Detailed description of complaints:** | | | | | | | | | |
| **Detailed description of complaints EU:** | | | | | | | | | |
|  | | | | | | | | | |
| Please indicate in each event if the complaints were due to: | | | | | | | | | |
|  | 1. User error |  | | | | | | | |
|  | 2. Procedure error |  | | | | | | | |
|  | 3. Product malfunction  4. Unanticipated events  5. Alleged direct harm caused to the patient or user of the device |  | | | | | | | |
| Are there any new emerging risks: | | Yes | |  | | No | |  | |
|  | |  | |  | |  | |  | |
| Discuss new risks if applicable : | | | | | | | | | |
| Has an external clinical expert been engaged to review the new risks? | | | | | | | | | |
| **Detailed description of complaints World wide:** | | | | | | | | | |
|  | | | | | | | | | |
| Please indicate in each event if the adverse events were due to: | | | | | | | | | |
| 1. | User error |  | | | | | | | |
| 2. | Procedure error |  | | | | | | | |
| 3. | Product malfunction |  | | | | | | | |
| **Are there any new emerging risks:** | | | **YES** | |  | | **NO** | |  |
| Discuss new risks if applicable : | | | | | | | | | |
|  | | | | | | | | | |
| If recalls occurred please discuss | | | | | | | | | |
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| **Section 2: Vigilance Reporting** | | | | |
| Has a vigilance report been sent to a Competent Authority: | Yes |  | No |  |
| Has a vigilance report been sent to NSAI: | Yes |  | No |  |
| Please list all vigilance reports with identifier number: | | | | |
|  | | | | |
| If yes, discuss each report in detail and provide copies of the reports, if not already submitted to NSAI: | | | | |
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| **Section 3: Risk Management** | | | | |
| Has the risk management file been updated to reflect these events: | Yes |  | No |  |
| Has the CER been updated to reflect these events: | Yes |  | No |  |
| Does the benefit of the product still outweigh the risk taking account “State of the Art” : | Yes |  | No |  |

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| **Section 4: Performance** | | | | |
| Is the device performing as intended, in line with the design of the device. | Yes |  | No |  |

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| **NSAI may request to see the**  **updated risk management documents and updated CER**. |