

**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 malfunction4. 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**. |