

**Medical Devices**

**Post Market Surveillance Application Form**

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| **Directive** | **NSAI File number**  |
| MDD (93/42/EEC) | 252.\_\_\_.\_\_\_ |
| AIMD (90/385/EEC) | 253.\_\_\_.\_\_\_ |
| MDR (2017/745) | 745.\_\_\_.\_\_\_ |

This NSAI post market surveillance form is drafted as per the recommendations of the guidance document MEDDEV 2.12/2 Guidelines on post market clinical follow-up studies and MDR 2017/745.

Ref. <https://ec.europa.eu/growth/sectors/medical-devices/guidance>.

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| **Product Name:** | Click here to enter text. |
| **Manufacturer:**  | Click here to enter text. |
| **Classification of Medical Device:**  | Click here to enter text. |
| **CE Mark Granted Date:** | Click here to enter text. |
| **Device commercialisation Date:**  | Click here to enter text. |
| **Countries available for sale/ distribution:** | Click here to enter text. |
| **Conditions of approval:** |
| 1. | Click here to enter text. | ***Or check*** N/A [ ]  |
| 2. | Click here to enter text. | ***Or check*** N/A [ ]  |
| 3. | Click here to enter text. | ***Or check*** N/A [ ]  |
| ***Add additional rows as required.*** |
| Legal Manufacturer’s Name | Click here to enter text. |
| Legal Manufacturer’s Address | Click here to enter text. |

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| **TABLE 1: POST-MARKET SURVEILLANCE IDENTIFICATION** |
| **Report No.** |  **DOC. ID # / Rev** | **Reviewed by** | **Report Date** |
| 1. Periodic safety update report
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| 1. Periodic safety update report
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| 1. Periodic safety update report
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| 1. Periodic safety update report
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***Add additional rows as required.***

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| **TABLE 2: POST MARKET SURVEILLANCE & PERIODIC SAFETY UPDATE REPORT**  |
| 1. Report ID(s):
 | Click here to enter text. |
| 1. Date product went on the market
 | Click here to enter text. |
| 1. Number of units sold
 | Click here to enter text. |
| 1. Estimate evaluation of the size and other characteristics of the population using the device
 | Click here to enter text. |
| 1. Estimate of the usage frequency of the device
 | Click here to enter text. |
| 1. Number of Complaints Total
 | Click here to enter text. |
| 1. Number of Complaints EU
 | Click here to enter text. |
| 1. Number of Complaints Rest of world
 | Click here to enter text. |
| 1. Complaint rate Total
 | Click here to enter text. |
| 1. Complaint rate EU
 | Click here to enter text. |
| 1. Complaint rate Rest of world
 | Click here to enter text. |
| 1. Number of Feedbacks
 | Click here to enter text. |
| 1. Feedback rates
 | Click here to enter text. |
| 1. Have there been any trends identified in relation to complaints. Provide details.
 | Click here to enter text. |
| 1. Number of all adverse events EU
 | Click here to enter text. |
| 1. Number of all adverse events Rest of World
 | Click here to enter text. |
| 1. Number of serious adverse events EU
 | Click here to enter text. |
| 1. Number of serious adverse events Rest of World
 | Click here to enter text. |
| 1. Number of unanticipated risks
 | Click here to enter text. |
| 1. Number of Vigilance reports to Competent Authority
 | Click here to enter text. |
| 1. Vigilance report rate
 | Click here to enter text. |
| 1. Number of World-wide reportable incidents
 | Click here to enter text. |
| 1. Number of product recalls EU
 | Click here to enter text. |
| 1. Number of product recalls World wide
 | Click here to enter text. |
| 1. Number of product withdrawal EU
 | Click here to enter text. |
| 1. Number of product withdrawal World wide
 | Click here to enter text. |
| 1. Number of Field Safety Notices
 | Click here to enter text. |
| 1. Number of Field Safety Corrective Action
 | Click here to enter text. |
| 1. Number of corrective actions from complaints or adverse events
 | Click here to enter text. |
| 1. List the current status of each corrective action
 | Click here to enter text. |
| 1. Who authored the Periodic safety update report
 | Click here to enter text. |
| 1. Please list the databases, registers or literature that has been searched
 | Click here to enter text. |
| 1. Please indicate the exact search terms and any limits, and the start and end dates for the literature search
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| 1. Has publicly available information regarding similar devices/generic device group been searched? State where in the report this has been addressed.
 | Click here to enter text. |
| 1. List the similar devices that have been reviewed and how these devices are deemed similar to the device under evaluation
 | Click here to enter text. |
| 1. Please submit the Post market clinical follow up plan in accordance with MDR Annex XIV Part B and MDCG 2020-7 template and state the document identifier
 | Click here to enter text. |
| 1. Please submit the Post market clinical follow up report in accordance with MDR Annex XIV Part B and MDCG 2020-8 template and state the document identifier
 | Click here to enter text. |
| 1. Please indicate where in the updated CER this information is captured
 | Click here to enter text. |
| 1. Please indicate where in the CER the findings of Post market clinical follow up are captured
 | Click here to enter text. |
| 1. What is the conclusion of the benefit risk determination and reference where in the Periodic safety update report and Clinical evaluation report this is captured
 | Click here to enter text. |
| 1. How often is the periodic safety update report updated
 | Click here to enter text. |
| 1. Identify the clinical expert, in accordance with the MEDDEV 2.7/1 Rev 4, Section 6.4, who reviewed this PMS
 | Click here to enter text. |
| 1. Please provide an up-to-date CV and justification of the clinical expert
 | Click here to enter text. |
| 1. Please provide an up-to-date CV and justification of the author
 | Click here to enter text. |
| 1. Please provide an up-to-date CV of the risk file owner
 | Click here to enter text. |
| 1. Please provide an up-to-date CV and justification for the individuals who performed the literature search and the second review of extracted data
 | Click here to enter text. |
| In the case of Complaints, Health and Safety Non-Conformances, CAPA’S, Risk Management File Updates related to Health and Safety, Recalls, Field Action or Advisory Notices, please provide details below: |
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| Type (CAPA, etc.) | ID / Rev. | Impact | Action Taken |
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Further details may be added below:Click here to enter text. |

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| **Section 1: Detailed description of QUALITY INCIDENTS / complaints:** |
| **Detailed description of Quality Incidents / Complaints (EU):** |
| (When submitting the data required, please clearly delineate between serious incidents and other incidents.)Provide details:      |
| Please indicate and provide quantity or Parts per Million (PPM) for each event if the complaints were due to the following:  |
| 1. User Error 2. Procedure error 3. Product malfunction4. Unanticipated events 5. Alleged direct harm caused to the patient or user of the device 6. Misuse and/or abnormal/off-label use of the device7. Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Click here to enter text. |
| Are there any new emerging risks: |  | [ ]  Yes | [ ]  No |
| Discuss new risks if applicable: Click here to enter text. |
| Discuss impact on existing risks: Click here to enter text. |
| Provide details: Click here to enter text. |
| Has an external clinical expert been engaged to review the new risks? | [ ]  Yes | [ ]  No |
| Provide details:  |
| If recalls or advisory notices or similar have occurred, please discuss. |
| Provide details:  |
| **Detailed description of complaints Worldwide:** |
| (When submitting the data required, please clearly delineate between serious incidents and other incidents.)Provide details: |
| Please indicate and provide quantity or Parts per Million (PPM) for each event if the adverse events were due to: 1. User error2. Procedure error3. Product malfunction4. Misuse and/or abnormal/off-label use of the device5. Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_Click here to enter text. |
| Are there any new emerging risks: | YES [ ]  | NO [ ]  |
| Discuss new risks if applicable: Click here to enter text. |
| Discuss impact to existing risks if applicable: Click here to enter text. |
| Provide details: Click here to enter text. |
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| Has an external clinical expert been engaged to review the new risks? | [ ]  Yes | [ ]  No |

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| Provide details:  |
| If recalls or advisory notices or similar have occurred, please discuss. |
| Provide details:      |

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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 and revision: |
| Click here to enter text. |
| If yes, discuss each report in detail and provide copies of the reports, if not already submitted to NSAI: |
| Click here to enter text. |
| For any recalls or field safety notices:Please provide copies of communication with the Competent AuthorityPlease provide evidence of final closure State the document identifier of each |
| Click here to enter text. |

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| **Section 3: Risk Management** |
| Has the risk management file been updated to reflect these risks/events:  | Yes | [ ]  | No | [ ]  |
| Has the risk management file been updated to reflect the occurrence and severity ratings and data provided in support of same? | Yes | [ ]  | No | [ ]  |
| Has the risk-benefit ratio been impacted and provide evidence for response? | Yes | [ ]  | No | [ ]  |
| Has the CER been updated to reflect these events:  | Yes | [ ]  | No | [ ]  |
| Please submit the updated CER and reference the section where the data from post market surveillance has been updated. If an updated CER is not being submitted please provide a justification for not updating the CER | Yes | [ ]  | No | [ ]  |
| Does the benefit of the product still outweigh the risk taking account “State of the Art” (review of similar devices on the market):Please provide evidence to support the response Discuss: Click here to enter text. | Yes | [ ]  | No | [ ]  |
| Has a Risk Owner with suitable *accountability,* *authority* and *independence* approved the risks assessments and conclusions?Please provide evidence in support of the response.Discuss: Click here to enter text. | 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 | [ ]  |
| Provide evidence including literature review, customer surveys, clinical follow-up reports, corrective actions, etc.: Click here to enter text. |
| Have all current regulations and guidance on Post-Market Surveillance been followed?  | Yes [ ]  | No [ ]  |
| Provide regulation / guidance document listing and revisions:Click here to enter text. |

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| **SEction 5:** **Summary of safety and clinical performance for implantabLE and class III DEVICES**  |
| Has the summary of safety and clinical performance been updated?  | Yes | [ ]  | No | [ ]  |
| If the summary of safety and clinical performance has not been updated please provide a justification  |  |   |  |  |
| Click here to enter text. |
| If yes, please submit the summary of safety and clinical performance for reviewPlease submit the traceability matrix with objective evidence of updates to risk management, SSCP, CEP, CER, IFU/labelling, PSUR, PMCF plan and report, as applicable |
| Click here to enter text. |

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| **SEction 6: Instructions for use**  |
| Has the instructions for use been updated  | Yes | [ ]  | No | [ ]  |
| If the Instructions for use has not been updated please provide a justification  |  |   |  |  |
| Click here to enter text. |
| If yes, please submit a red line version of the Instructions for use : |
| Click here to enter text. |

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| **NSAI may request to see the** **Updated Risk Management File and Supporting Data, or other information to support your application**. |