

**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 |  |  |  |
| 1. Periodic safety update report |  |  |  |
| 1. Periodic safety update report |  |  |  |
| 1. Periodic safety update report |  |  |  |

***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 |  |
| 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: | |
| |  |  |  |  | | --- | --- | --- | --- | | Type (CAPA, etc.) | ID / Rev. | Impact | Action Taken | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  |   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 malfunction  4. 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 device  7. 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 error  2. Procedure error  3. Product malfunction  4. Misuse and/or abnormal/off-label use of the device  5. 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. | | | | | |
| |  |  |  | | --- | --- | --- | | 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: | | | | | |

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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 Authority  Please 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 review  Please 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**. |