## Appendix 1 – Post-Market Surveillance Plan

| | |
|---|---|
| Date: | |
| Product: | |

| No. | [illegible] | [illegible] | Name of the [illegible] |
|---|---|---|---|
| 1 | Serious incidents and field safety corrective actions: [illegible] | | |
| 2 | Non-serious [illegible] action system) | | |
| 3 | Trend reporting (data analysis) | | |
| 4 | Scientific or technical [illegible] safety data | | |
| 5 | Feedback and customer complaints [illegible] | | |
| 6 | [illegible] | | |

| | |
|---|---|
| Post-market Clinical [illegible] | |

List of all procedures from QMS covering these PMS elements:

**Commented [13A1]:** Delete or add data from the table as applicable to your company.

**Commented [13A3]:** The following documents can be used:
- Registry and Status of Corrective and Preventive Actions, you can find a template for this document in folder "21_Corrective_and_Preventive_Action" of the ISO 13485 & MDR Integrated Documentation Toolkit
- Registry of Customer Complaints, you can find a template for this document in folder "08_Customer_Complaints_and_Feedback" of the ISO 13485 & MDR Integrated Documentation Toolkit
- Registry of Reports to the Authorities, you can find a template for this document in folder "08_Customer_Complaints_and_Feedback" of the ISO 13485 & MDR Integrated Documentation Toolkit

**Commented [13A2]:** E.g. [illegible]

**Commented [13A4]:** E.g. [illegible]

**Commented [13A5]:** The following documents can be used:
- Registry and Status of Corrective and Preventive Actions, you can find a template for this document in folder "21_Corrective_and_Preventive_Action" of the ISO 13485 & MDR Integrated Documentation Toolkit
- Registry of Customer Complaints, you can find a template for this document in folder "08_Customer_Complaints_and_Feedback" of the ISO 13485 & MDR Integrated Documentation Toolkit

**Commented [13A6]:** E.g. Management representative, department managers

**Commented [13A7]:** The following document can be used: Data Analysis Report, you can find a template of this document in folder "22_Data_Analysis" of the ISO 13485 & MDR Integrated Documentation Toolkit.

**Commented [13A8]:** E.g. Design manager, QA Manager, Safety officer

**Commented [13A9]:** The following document can be used: Periodic Safety Update Report, you can find a template for this document in folder "18_Post_market_Surveillance" of the ISO 13485 & MDR Integrated Documentation Toolkit.

**Commented [13A10]:** E.g. [illegible] Investigator

**Commented [13A11]:** The following document can be used: Registry of Customer Complaints, you can find a template for this document in folder "08_Customer_Complaints_and_Feedback" of the ISO 13485 & MDR Integrated Documentation Toolkit.

**Commented [13A12]:** E.g. Salesperson

**Commented [13A13]:** The following document can be used: Post-market Surveillance Report, you can find a template for this document in folder "18_Post_market_Surveillance" of the ISO 13485 & MDR Integrated Documentation Toolkit.

**Commented [13A14]:** Please include the identification number [illegible]

| No. | [illegible] | [illegible] |
|---|---|---|
| | | |

[name]

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[signature]

**Commented [13A15]:** Only necessary if document is in paper form.