Post Market Surveillance (PMS) Report

Device Name/ Model Name

Document Authorisation

Task	Name	Signature	Date
Document Prepared By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Reviewed By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Approved By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY

Revision History

Version	Release Date	Change History
Version Number	DD-MM-YYYY	Changes made on the particular release date mentioned in previous column.

Table of Contents

1. Executive Summary

Provide a brief overview of the PMS report, summarizing the report's purpose, key findings, and any significant conclusions. Mention any ongoing issues or improvements observed in the field.

2. Device Description

Include a concise description of the device, its intended purpose, indications for use, and any relevant design or material features. If there have been modifications or updates to the device, note them here.

- **Device Name**: [Name]
- **Intended Use**: [Briefly describe intended use]
- **Indications**: [List primary indications]

3. Post Market Surveillance Objectives

State the objectives of the PMS, ensuring they align with the requirements of EU MDR, particularly Article 83. Common objectives include monitoring safety, assessing risks, and evaluating performance under real-world conditions.

- Example Objectives:
  - Ensure continuous compliance with EU MDR requirements.
  - Collect and analyze post-market data to identify adverse events or risks.
  - Implement corrective actions if needed.

4. Data Collection and Analysis

Details of the manufacturer: Legal manufacturer, Person Responsible for Regulatory compliance, Authorised representative.

4.1. Sources of Data

Identify the sources of data used in PMS activities, such as:

- Customer feedback and complaints
- Adverse events reported
- Market feedback
- Scientific literature review
- Surveillance reports from authorities

4.2. Methodology of Data collection

Describe the methodologies used to gather data. This may include surveys, review of complaints, and vigilance reporting.

4.3. Data Analyst

Provide a summary of the data analysis, including:

- Complaint trends
- Frequency of adverse events
- Device performance vs. expectations
- Comparative data with similar devices on the market

5. Summary of Findings

Summarize key findings from data analysis, including:

- Rate and type of adverse events
- Any unanticipated risks
- Identified trends in complaints or performance
- Deviations from expected performance

6. Actions taken

List actions taken as a result of PMS findings, such as:

- Corrective or preventive actions
- Design modifications
- Updated risk assessments
- Changes to labelling or instructions for use

7. Conclusion

Provide a brief conclusion summarizing:

- Overall device performance and safety
- Compliance with EU MDR requirements
- Recommendations for future PMS activities

8. Appendices

Add any additional information, such as:

- Raw data tables
- Customer feedback summaries
- Detailed adverse event reports