Periodic Safety Update Report (PSUR)

Company/ Manufacturer Name

Device Name/ Model Name

DD-MM-YYYY – DD-MM-YYYY

Notified Body Name and Number	Enter the Notified Body Name and Number
PSUR reference number assigned by the manufacturer	Enter the PSUR Reference Number given by the Manufacturer
Version number of the PSUR	Enter the Version Number of the PSUR

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. Introduction

This report has been prepared in accordance with Article 86 of Regulation (EU) 2017/745 on medical devices (EU MDR) to summarize safety and performance information for the device. This PSUR covers data from **[start date]** to **[end date]**.

2. Device Description

2.1. Device Overview

Briefly describe the device, its intended use, classification, and main components.

2.2. Indications for Use

Summarize intended indications.

2.3. Clinical Background

Overview of clinical relevance, target patient group, and use environment.

3. Safety and Performance information

3.1. Summary of Vigilance Data

Provide an analysis of adverse events reported during the period, including:

- **Total Adverse Events Reported**:
- **Serious Incidents**: Summarize serious incidents (e.g., death, life-threatening events).
- **Non-serious Incidents**: Overview of non-serious incidents.

3.2. Trend Analysis

- **Expected vs. Observed Rates**: Compare anticipated incident rates with observed rates.
- **Identified Trends**: Describe any new or ongoing trends, e.g., increased device malfunction rate in specific patient demographics.

3.3. Field Safety Corrective Actions (FSCAs)

- **Overview of FSCAs**: Document any Field Safety Notices, product recalls, or modifications.
- **Corrective Measures and Outcomes**: Summarize actions taken to address identified risks and their effectiveness.

3.4. Literature Review

- **Search Criteria and Databases**: Summarize the sources and criteria used.
- **Relevant Findings**: Note findings related to device safety, performance, or newly identified risks.

4. Benefit-Risk Assessment

Conduct a benefit-risk evaluation based on current performance and safety data:

- **Benefit Summary**: Outline known benefits as per intended use and target population.
- **Risk Summary**: Summarize significant risks and adverse outcomes identified.
- **Overall Benefit-Risk Conclusion**: Assess whether benefits outweigh risks given current data.

5. Conclusions and Recommendations

Summarize the main findings of the PSUR and any recommendations for continued safety and performance monitoring. Outline any actions to be taken to mitigate identified risks.

6. Appendices

Attach relevant data, supporting documentation, or additional analyses:

- **Appendix A**: Summary of Adverse Event Reports
- **Appendix B**: Field Safety Corrective Action Documentation
- **Appendix C**: Literature Review Details and Findings