Post Market Clinical Follow-up (PMCF) Plan

Device Name/ Model Name

PMCF Plan Number:	*Information required*
PMCF Plan Date:	*Information required*
PMCF Plan Version:	*Information required*

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 section outlines the rationale for the PMCF plan, emphasizing the importance of ongoing data collection to ensure the continued safety and performance of the device in the post-market phase.

2. Objective

This section outlines the rationale for the PMCF plan, emphasizing the importance of ongoing data collection to ensure the continued safety and performance of the device in the post-market phase.

3. Product information

3.1. Device description

Provide a brief description of the device, including its key features and intended purpose.

3.2. Intended Use

Outline the intended use of the device, including target patient population and clinical indications.

4. Manufacturer Contact details

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

5. Activities related to PMCF

Provide details on how the gathered data will be evaluated and interpreted to assess the safety, performance, and clinical benefits of the device. This section is essential for ensuring that the literature search is rigorous and supports evidence-based conclusions in the Clinical Evaluation Report (CER).

5.1. Data Collection Methods

Describe the methods for collecting data, including observational studies, surveys, or analysis of existing data.

5.2. Target population

Define the population from which data will be collected, including inclusion and exclusion criteria.

5.3. Data Management and Analysis

Outline how the collected data will be managed, analyzed, and reported.

6. Summary of the PMCF Activities

6.1. Data sources

List the databases used for the search (e.g., PubMed, Embase, Cochrane Library) and justify the selection.

6.2. Search limit

In a literature search report, **search limits** are criteria applied to refine and focus the search results to ensure relevance and quality. Under EU MDR, search limits help narrow the literature to studies most applicable to the medical device's clinical evaluation.

6.3. Search terms

Provide details of search terms used, including product-related keywords, clinical terms, and any limitations (e.g., date range, language).

6.4. Inclusion and Exclusion criteria

Define the criteria for including or excluding studies, considering aspects like study design, relevance to product, population, and language.

6.5. Assessment criteria

Describe the process for screening and selecting relevant studies, explaining the steps and criteria used.

7. Evaluation of clinical data relating to equivalent or similar devices

Describe the goal of evaluating clinical data from equivalent or similar devices, such as validating the safety and performance of your device in the context of existing literature. Conclude with a brief summary of how the evaluation of clinical data from equivalent devices supports the ongoing safety and efficacy of your device.

8. References

Clinical Evaluation Report (Mention version) of Device Name in the QMS.

9. Conclusion

Summarize the importance of the PMCF plan in ensuring ongoing compliance and safety of the device.

10. Estimated date of the PMCF evaluation report

Mention Estimated date of the PMCF evaluation report for the subject device.

When the manufacturer plans to have the first report. The timelines shall be defined quarterly or at least yearly