[Organization logo]

[Organization name]

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PROCEDURE FOR POST-MARKET SURVEILLANCE SYSTEM

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

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Distribution list

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Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. Purpose, scope and users

The purpose of this Procedure is to provide a post-market surveillance system so that [organization name] knows at all times what happens to medical device once they go out of production.

This Procedure applies to all processes within the Quality Management System (QMS).

Users of this document are top management, Management Representative and person responsible for regulatory compliance (PRRC).

2. Reference documents

- ISO 13485:2016 standard, clauses 7.2.3, 8.2.1, 8.2.2, 8.2.3, and 8.3.3
- ISO 14971:2019, clause 10
- MDR 2017/745, articles 10(10), 15, 83, 84, 85, 86, Annex III, Annex IX – Chapter I, and Annex IV – Part B
- MEDDEV 2.12/2 rev. 2
- MDCG 2020-7 Post-Market Clinical Follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
- Sales Procedure
- Procedure for Risk Management
- Procedure for Vigilance and Adverse Event Investigation and Reporting
- Procedure for Corrective and Preventive Action
- Procedure for Data Analysis
- Quality Manual

3. Post-market surveillance

3.1. Gathering the data and Post-Market Surveillance Plan

PRRC is responsible for preparing the Post-Market Surveillance Plan, and assigning tasks for gathering the following data needed for Post-market surveillance:

- Serious incidents and field safety corrective actions
  - Field safety corrective actions (type/rate)
  - [illegible]
  - [illegible]
- [illegible]
- Trend reporting (Data analysis)
- Scientific or technical literature review
  - Summary of new performance data
  - [illegible]

Commented [AES4]: Include the name of your organization.

Commented [AES5]: If person responsible for regulatory compliance is the same person as Management Representative, you can delete this.

Commented [AES6]: Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES7]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "08_Sales".

Commented [AES8]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "07_Risk_Management".

Commented [AES9]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "19_Adverse_Event_Investigation".

Commented [AES10]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "25_Corrective_and_Preventive_Action".

Commented [AES11]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "26_Data_Analysis".

Commented [AES12]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

- Feedback and customer complaints
  - Number of sales
  - Number of uses
  - Number of patients
  - [illegible]
  - [illegible]
  - [illegible]
- [illegible]

PRRC is responsible for organizing PMS review meetings and for informing all persons responsible for gathering data about the date of the meeting. Each person responsible for gathering data must gather the data, write a brief report of the data analysis, and document a conclusion. The results of the PMS review meeting (PMS Report) are an input for Management review.

[illegible]

3.2. Post-market surveillance report

PMS reports are the output of the PMS review meetings for class I medical devices (class I, class Is, class Ir and class Im). PRRC is responsible for leading the discussion during the PMS review meeting and for completing the PMS Report. PMS reports must include a conclusion for the period when the next PMS review will be conducted.

[illegible]

A PMS Report may raise an issue that requires immediate action (e.g., it may identify a previously unidentified potential for serious injury or death). In this instance, [job title] must initiate corrective action.

[illegible]

3.3. Periodic Safety Update Report (PSUR)

For class IIa, class IIb and class III devices, PRRC is responsible to prepare a Periodic Safety Update Report (PSUR) for each device and, where relevant, for each category or group of devices. This report must summarize the results and conclusions of the analyses of the post-market surveillance data about classes IIa, IIb and III, gathered from Post-Market Surveillance Plan.

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Commented [AES14]: This needs to be someone from the top

Commented [AES15]: E.g., if there were some problems with

Commented [AES16]: E.g., in six months, in one year.

Commented [AES17]: Include one or more responsible

Commented [AES18]: Include the number of days that will be

Commented [AES19]: Adapt to the organization's practice.

In addition to the elements listed for the PMS report, PSUR also requires the following: (1) conclusions from the risk-benefit consideration and estimation of population size using the device, and (2) the usage frequency in the case of reusable devices.

The frequency of preparing PSUR is every two years for class IIa, and once a year for class IIb and class III.

PSUR is an input to Management review.

This table represent the difference between PMS report and PSUR:

	PMS report	PSUR			
Class of device	Class I	Class IIa	Class IIb	Class IIa, IIb implantable	Class III
Content	Summary and conclusion of surveillance data analysis				
	Rationale and description of any preventive and corrective actions				
	-	Volume of sales of device and estimate evaluation of the size and other characteristics of the population using it, where practicable usage frequency of the device			
	-	Main findings from post-market clinical follow-up			
	-	Conclusion of risk-benefit determination			
Periodicity of revision	As needed, based on new input	As needed, at least biennially	At least annually	At least annually	At least annually

3.4. Post-market clinical follow-up

Post-market surveillance aims to continuously verify the benefits of medical devices and to identify previously unknown risks by observing and analyzing daily practical usage. If regular market surveillance does not provide sufficient data, post-market clinical follow-up studies regarding the manufacturer may become necessary.

PRRC is responsible for deciding whether it is necessary to initiate a post-market clinical follow-up, and to prepare Post-Market Clinical Follow-up (PMCF) Plan.

PRRC is responsible for proactive collection and evaluation of clinical data from the use in/on humans of a CE marked device with the aim to:

- confirming the safety and performance of the device throughout its expected lifetime
- identifying previously unknown side-effects and monitoring the identified side-effects and contraindications
- identifying and analyzing emergent risks on the basis of factual evidence
- ensuring the continued acceptability of the benefit-risk ratio

- identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct

Commented [AES20]: These items are all mandatory according

PRRC is responsible to initiate PMCF in coordination with top management, clinical evaluator and QA Manager in following circumstances:

- innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel
- significant changes to the products or to its intended use for which pre-market clinical Evaluation and re-certification has been completed
- [illegible]
- [illegible]
- high risk target populations e.g., pediatrics, elderly
- severity of disease/treatment challenges
- [illegible]
- [illegible]
- results from any previous clinical investigation, including adverse events or from post-market surveillance activities
- identification of previously unstudied subpopulations which may show different benefit/risk-ratio (e.g., hip implants in different ethnic populations)
- [illegible]
- [illegible]
- interaction with other medical products or treatments
- verification of safety and performance of device when exposed to a larger and more varied population of clinical users
- [illegible]
- [illegible]

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PRRC is responsible is to prepare PMCF Plan which must contain the following information:

- the period of study,
- Plan number,
- [illegible]
- [illegible]
- device information,
- confirmation or disproval of acceptability of the previously identified risks, discovery of new risk, and evaluation of clinical safety and performance,
- [illegible]
- [illegible]
- data to be collected,
- special control measures needed to be considered and adopted during the study.

The PMCF Plan is an input for Management review.

4. Managing records kept on the basis of this document

Record name	Code	Storage			
		[illegible]	[illegible]	[illegible]	[illegible]
Post-Market Surveillance Plan	PR21.1	[illegible]	[illegible]	[illegible]	[illegible]
Post-Market Surveillance Report	PR21.2	[illegible]	[illegible]	[illegible]	[illegible]
Periodic Safety Update Report	PR21.3	[illegible]	[illegible]	[illegible]	[illegible]
Post-Market Clinical Follow-up Plan	PR21.4	[illegible]	[illegible]	[illegible]	[illegible]

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5. Appendices

- Appendix 1 – Post-Market Surveillance Plan
- Appendix 2 – Post-Market Surveillance Report
- [illegible]
- [illegible]

[job title]
[name]

[signature]

Commented [AES25]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.