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**PROCEDURE FOR POST-MARKET SURVEILLANCE SYSTEM**

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# 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).

# 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

# Post-market surveillance

## 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)
  + …

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