**Post-Market Clinical Follow-Up (PMCF) Plan**

For

[Device Name]

Manufacturer Name: [Manufacturer name]

Document Number: XXXX

Revision: XXXX

Date: DD/MM/YYYY

# Approval

**Reviewer**

|  |
| --- |
|  |
| Name: | Date: |
| Title: | Signature: |

**Approver**

|  |
| --- |
|  |
| Name: | Date: |
| Title: | Signature: |
|  |
| Name: | Date: |
| Title: | Signature: |

# Revision history

Table 1: History of revisions

| **Revision** | **Revision date** | **Description of change** | **Revised by** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Manufacturer contact details

The following table includes the manufacturer details.

Table 2: Contact information

| **Contact information** | **Description** |
| --- | --- |
| Legal manufacturer name: |  |
| Address: |  |
| Single Registration Number (SRN): |  |
| Person responsible for regulatory compliance (PRRC): |  |
| E-mail: |  |
| Phone: |  |
| Fax: |  |
|  |  |
| Authorized Representative: |  |
| Address: |  |
| Contact Person: |  |
| E-mail: |  |
| Phone: |  |
| Fax: |  |

# Medical Device description and specification

## General medical device details.

The following table includes the general information on [Device name] (hereafter named [device short name]).

Table 3: Medical device details

| **Medical device information** | **Description** |
| --- | --- |
| Product or trade name |  |
| Model and type | XXXX / See appendix I |
| Basic UDI-DI |  |
| EMDN code (CND code) | XXXX / See appendix I |
| Certificate number (if applicable) |  |
| Class and classification rule | Class X under Rule Y / Refer to appendix I |
| Expected lifetime | XXXX / See appendix I |
| Novelty: |  |
| * Novel product:
 | Yes/No if yes describe the novelty |
| * Novel related clinical procedure:
 | Yes/No if yes describe the novelty |

## General description of the device

Copy/paste from the TD (or CER)

## List and description of any variants and/or configurations covered by this plan

Copy/paste from the TD (or CER)

## List of any accessories covered by this plan

Copy/paste from the TD (or CER)

## Intended purpose

Copy/paste from the IFU (or TD if no IFU)

## Intended users

Copy/paste from the IFU (or TD if no IFU)

## Intended patient population

Copy/paste from the IFU (or TD if no IFU)

## Medical condition(s)

Copy/paste from the IFU (or TD)

## Indications

Copy/paste from the IFU (or TD if no IFU)

## Contraindications

Copy/paste from the IFU (or TD if no IFU)

## Warnings

Copy/paste from the IFU (or TD if no IFU)

# Activities related to PMCF: general and specific methods and procedures

The following table describes the planned general and specific methods and procedures of PMCF for [device short name]. All planned PMCF activities are further described in the next sections.

This PMCF plan covers the period from YYYY/MM/DD to YYYY/MM/DD

This period should be aligned with the PMS plan

Table 4: Description of PMCF activities for [device short name]

| **Item** | **PMCF activity** | **Objective** | **Description** | **Rationale to be appropriate and known limitations** | **Timelines** |
| --- | --- | --- | --- | --- | --- |
| **General procedures and methods of PMCF** |
| C1 | Screening of scientific literature for the subject device | Select the appropriate objective(s)* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device
 | Procedure: refer to an existing QMS procedure (if applicable)Description: Collection of scientific literature on [device short name] through implementation of literature search methodology via the following databases:* Embase
* PubMed
* Cochrane Library
* Google Scholar
* EU Clinical Trials Register
* Clinicaltrials.gov
* XXXX
 | Rationale:Include a summary of the rationale for appropriatenessKnown limitations: e.g., incomplete follow up, missing data | Collection:YYYY / QX-YYYY / MM-YYYYAnalysis:YYYY / QX-YYYY / MM-YYYYReport:YYYY / QX-YYYY / MM-YYYY |
| C2 | Screening of vigilance and recalls in publicly available database for the subject device | Select the appropriate objective(s)* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device
 | Procedure: refer to an existing QMS procedure (if applicable)Description: Collection of vigilance/recall reported for [device short name] in the following publicly available databases:* FDA MAUDE
* FDA Medical Device Recalls
* ANSM safety information
* Bfarm Field Corrective Actions
* MHRA Alerts, recalls and safety information: drugs and medical devices
* SwissMedic – FSCA and recall
* DAEN (Database of Adverse Event Notifications) - medical devices
* SARA (System for Australian Recall Actions)
* Canadian recalls and safety alerts
* XXXX
 | Rationale:Include a summary of the rationale for appropriatenessKnown limitations: e.g., incomplete follow up, missing data | Collection:YYYY / QX-YYYY / MM-YYYYAnalysis:YYYY / QX-YYYY / MM-YYYYReport:YYYY / QX-YYYY / MM-YYYY |
| **Specific procedures and methods of PMCF** |
| C3 | Device registry | Select the appropriate objective(s)* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device
 | Procedure: refer to an existing QMS procedure (if applicable)Description: consultation of device registry XXXX indicate the name of the registry to collect clinical evidence that supports the safety and performance of [device short name] | Rationale:Include a summary of the rationale for appropriatenessKnown limitations: e.g., incomplete follow up, missing data | Collection:YYYY / QX-YYYY / MM-YYYYAnalysis:YYYY / QX-YYYY / MM-YYYYReport:YYYY / QX-YYYY / MM-YYYY |
| C4 | PMCF investigation | Select the appropriate objective(s)* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device
 | Procedure: refer to an existing QMS procedure (if applicable)Description: implementation of PMCF investigation to collect clinical evidence that supports the safety and performance of [device short name] | Rationale:Include a summary of the rationale for appropriatenessKnown limitations: e.g., incomplete follow up, missing data | Collection:YYYY / QX-YYYY / MM-YYYYAnalysis:YYYY / QX-YYYY / MM-YYYYReport:YYYY / QX-YYYY / MM-YYYY |
| C5 | PMCF patient/user survey | Select the appropriate objective(s)* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device
 | Procedure: refer to an existing QMS procedure (if applicable)Description: The PMCF study under the form of collection of patient/user survey is intended to collect clinical data for specific safety and/or performance questions on [device short name] | Rationale:Include a summary of the rationale for appropriatenessKnown limitations: e.g., incomplete follow up, missing data | Collection:YYYY / QX-YYYY / MM-YYYYAnalysis:YYYY / QX-YYYY / MM-YYYYReport:YYYY / QX-YYYY / MM-YYYY |
| C6 | Select the appropriate activity* PMCF user survey (for a specific purpose)
* PMCF patient survey (for a specific purpose)
* PMCF investigation
* Device registry

… | Select the appropriate objective(s)* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device
 | Procedure: refer to an existing QMS procedure (if applicable)Description: include a summary of the method/procedure that will be further described in the next sections | Rationale:Include a summary of the rationale for appropriatenessKnown limitations: e.g., incomplete follow up, missing data | Collection:YYYY / QX-YYYY / MM-YYYYAnalysis:YYYY / QX-YYYY / MM-YYYYReport:YYYY / QX-YYYY / MM-YYYY |

## Screening of scientific literature for the subject device

### Type of procedures and methods

General procedure and method.

### Objective

Copy/paste the information from the summary table

### Description

A literature search will be implemented to detect the published and unpublished articles related to the [device short name] and bring clinical evidence for the demonstration of safety and performance.

The literature search methodology will be carried out in compliance with Section A5 of MEDDEV 2.7/1 rev.4. Research questions will be constructed using a PICO (Populations, Interventions, Comparators, Outcomes) process to justify the selection of relevant keywords.

The literature search will be applied in the following databases:

* Embase
* PubMed
* Cochrane Library
* Google Scholar
* EU Clinical Trials Register
* Clinicaltrials.gov
* XXXX

In the literature databases, the search queries will be defined using the selected keywords in a way to match with the language of each database used. The queries will have to incorporate the relevant search limitations (e.g., article type, language, as applicable).

The result of literature search will be a list of articles that will be screened in two stages:

* Level-1 screening is based on the titles and abstracts
* Level-2 screening is based on the full articles

The screening process consists of the review of each collected article to confirm if it should be included or excluded based on the inclusion/exclusion criteria.

The literature search will be implemented according to a literature search protocol that is defined based on the literature search protocol from the last clinical evaluation report (CER). The results will be documented in a literature search report.

The post-market clinical follow-up (PMCF) evaluation report for [device short name] will analyze and summarize the findings resulting from the literature search report.

### Rationale for appropriateness of the procedure/method

A rationale that supports how the method is appropriate, needs to be described.

### Limitations

Further describe the limitations if applicable, as compared to the summary table above.

## Screening of vigilance and recalls in publicly available database for the subject device

### Type of procedures and methods

General procedure and method.

### Objective

Copy/paste the information from the summary table

### Description

A vigilance / recall search will be implemented to detect the clinical risks (i.e., device problem, patient problems) related to [device short name] and bring additional clinical evidence for the demonstration of safety and performance.

The vigilance / recall search methodology will be carried out using an approach similar to the literature search methodology. Research questions will be constructed using a PICO process to justify the selection of relevant keyword.

The vigilance / recall search will be applied in the following databases:

* FDA MAUDE
* FDA Medical Device Recalls
* ANSM safety information
* Bfarm Field Corrective Actions
* MHRA Alerts, recalls and safety information: drugs and medical devices
* SwissMedic – FSCA and recall
* DAEN (Database of Adverse Event Notifications) - medical devices
* SARA (System for Australian Recall Actions)
* Canadian recalls and safety alerts
* XXXX

In the vigilance / recall databases, the search queries will be defined using the selected keywords in a way to match with the language of each database used. The queries will have to incorporate the relevant search limitations (e.g., search period).

The result of vigilance / recall searches will be a list of events that will be screened to determine if applicable to [device short name].

The vigilance / recall search will be implemented according to a vigilance / recall search protocol that is defined based on the vigilance / recall search protocol from the last CER. The results will be documented in a vigilance / recall search report.

The post-market clinical follow-up (PMCF) evaluation report for [device short name] will analyze and summarize the findings resulting from the vigilance / recall search report.

### Rationale for appropriateness of the procedure/method

A rationale that supports how the method is appropriate, needs to be described.

### Limitations

Further describe the limitations if applicable, as compared to the summary table above.

## Device registry

### Type of procedures and methods

Specific procedure and method

### Objective

Copy/paste the information from the summary table

### Description

Clinical data from the registry XXXX Registry name relevant to [device short name] /or medical conditions treated by [device short name], will be collected according to the registry consultation protocol under XXXX rev.Y Document Number. Intermediary results will be documented in intermediary registry reports and final results will be documented in a final registry report.

The information relevant to the registry consultation is summarized in the following table with the estimated schedule.

| **Device registry requirements** | **Device registry details** |
| --- | --- |
| Study design | Registry |
| Study objective |  |
| Geographic area |  |
| Population |  |
| Number of patients enrolled |  |
| Inclusion/exclusion criteria |  |
| Control group and justification |  |
| Study method |  |
| Follow-up duration |  |
| Endpoints |  |
| Need of notification/approval: | [ ] Ethic committee (justification if not): |
| [ ] NB (justification if not): |
| [ ] CA (justification if not): |
| Estimated schedule |

|  |  |
| --- | --- |
| **Activity** | **Schedule** |
| Approval of Registry consultation protocol: |  |
| Ethic Committee approval: |  |
| CA approval:  |  |
| Recruitment: |  |
| Intermediary results (collection of data, analysis, intermediary report) |  |
| Intermediary results (collection of data, analysis, intermediary report) |  |
| Intermediary results (collection of data, analysis, intermediary report) |  |
| Final results (collection of data, analysis, final report) |  |

 |

### Rationale for appropriateness of the procedure/method

Per MDCG 2020-7, the following should be considered for specific procedures/methods:

* the justification for sample size, timescales and endpoints
* justification for comparator, on the basis of intended purpose and state of the art
* justification of the study design on the basis of all of the above, and why it is sufficient to ensure representative patient populations and provide for adequate controls on sources of bias (an evaluation of the potential sources of bias should form part of this)
* a statistical justification for the expected quality of outcomes, and justification for why this is satisfactory in light of the residual risks.

### Limitations

Further describe the limitations if applicable, as compared to the summary table above.

## PMCF investigation

### Type of procedures and methods

Specific procedure and method

### Objective

Copy/paste the information from the summary table

### Description

The PMCF investigation has been defined based on the PMCF investigation protocol under XXXX rev.Y Document Number. Intermediary results will be documented in intermediary PMCF investigation reports and final results will be documented in a final PMCF investigation report.

The information relevant to the PMCF investigation is summarized in the following table with the estimated schedule.

| **PMCF investigation requirements** | **PMCF investigation details** |
| --- | --- |
| Study design |  |
| Study objective |  |
| Geographic area |  |
| Population |  |
| Number of patients enrolled |  |
| Inclusion/exclusion criteria |  |
| Control group and justification |  |
| Investigator(s) |  |
| Investigation site(s) |  |
| Study method |  |
| Follow-up duration |  |
| Endpoints |  |
| Need of notification/approval: | [ ] Ethic committee (justification if not): |
| [ ] NB (justification if not): |
| [ ] CA (justification if not): |
| Estimated schedule |

|  |  |
| --- | --- |
| **Activity** | **Schedule** |
| Approval of PMCF investigation protocol: |  |
| Ethic Committee approval: |  |
| CA approval:  |  |
| Recruitment: |  |
| Intermediary results (collection of data, analysis, intermediary report) |  |
| Intermediary results (collection of data, analysis, intermediary report) |  |
| Intermediary results (collection of data, analysis, intermediary report) |  |
| Final results (collection of data, analysis, final report) |  |

 |

### Rationale for appropriateness of the procedure/method

Per MDCG 2020-7, the following should be considered for specific procedures/methods:

* the justification for sample size, timescales and endpoints
* justification for comparator, on the basis of intended purpose and state of the art
* justification of the study design on the basis of all of the above, and why it is sufficient to ensure representative patient populations and provide for adequate controls on sources of bias (an evaluation of the potential sources of bias should form part of this)
* a statistical justification for the expected quality of outcomes, and justification for why this is satisfactory in light of the residual risks.

### Limitations

Further describe the limitations if applicable, as compared to the summary table above.

## PMCF patient/user survey

### Type of procedures and methods

Specific procedure and method

### Objective

Copy/paste the information from the summary table

### Description

The PMCF study is intended to collect clinical data for the patient/user perception for XXXX describe the specific concern identified.

The PMCF study has been defined based on the PMCF study protocol under XXXX rev.Y Document Number. Intermediary results will be documented in intermediary PMCF study reports and final results will be documented in a final PMCF study report.

The information relevant to the PMCF study is summarized in the following table with the estimated schedule.

| **PMCF study requirements** | **PMCF study details** |
| --- | --- |
| Study design | Patient/User survey |
| Study objective |  |
| Geographic area |  |
| Population |  |
| Number of patients/users enrolled |  |
| Inclusion/exclusion criteria |  |
| Control group and justification |  |
| Investigator(s) |  |
| Investigation site(s) |  |
| Study method |  |
| Follow-up duration |  |
| Endpoints |  |
| Need of notification/approval: | [ ] Ethic committee (justification if not): |
| [ ] NB (justification if not): |
| [ ] CA (justification if not): |
| Estimated schedule |

|  |  |
| --- | --- |
| **Activity** | **Schedule** |
| Approval of PMCF study protocol: |  |
| Ethic Committee approval: |  |
| CA approval:  |  |
| Recruitment: |  |
| Intermediary results (collection of data, analysis, intermediary report) |  |
| Intermediary results (collection of data, analysis, intermediary report) |  |
| Intermediary results (collection of data, analysis, intermediary report) |  |
| Final results (collection of data, analysis, final report) |  |

 |

### Rationale for appropriateness of the procedure/method

Per MDCG 2020-7, the following should be considered for specific procedures/methods:

* the justification for sample size, timescales and endpoints
* justification for comparator, on the basis of intended purpose and state of the art
* justification of the study design on the basis of all of the above, and why it is sufficient to ensure representative patient populations and provide for adequate controls on sources of bias (an evaluation of the potential sources of bias should form part of this)
* a statistical justification for the expected quality of outcomes, and justification for why this is satisfactory in light of the residual risks.

### Limitations

Further describe the limitations if applicable, as compared to the summary table above.

## PMCF Activity C6 copy/paste the general procedure indicated in the summary table

### Type of procedures and methods

Specific procedure and method

### Objective

Copy/paste the information from the summary table

### Description

Further describe the PMCF activity

### Rationale for appropriateness of the procedure/method

Per MDCG 2020-7, the following should be considered for specific procedures/methods:

* the justification for sample size, timescales and endpoints
* justification for comparator, on the basis of intended purpose and state of the art
* justification of the study design on the basis of all of the above, and why it is sufficient to ensure representative patient populations and provide for adequate controls on sources of bias (an evaluation of the potential sources of bias should form part of this)
* a statistical justification for the expected quality of outcomes, and justification for why this is satisfactory in light of the residual risks.

### Limitations

Further describe the limitations if applicable, as compared to the summary table above.

# Reference to the relevant parts of the technical documentation

## Relevant information from the clinical evaluation report

This PMCF plan for [device short name] is defined based on the outputs of the clinical evaluation report (CER) XXXX rev.Y approved on DD Month YYYY.

The relevant information from the CER to be specifically analyzed, followed-up, and evaluated are gathered in the following table.

Table 5: Relevant information from the CER

| **Relevant information from the CER** | **CER section(s)** |
| --- | --- |
| Indicate the weaknesses/gaps with the clinical evaluation (e.g., the CER is based on the equivalence and the results need to be confirmed with the clinical data on the subject device, limited clinical data for a size of the device range) |  |
| Indicate the specific risks identified in the CER to be monitored |  |
| Indicate the known undesirable side-effects to be monitored |  |
| Indicate the known misuse or off label used to be monitored |  |
| … |  |

/or

No relevant information from the clinical evaluation report needs to be considered in this PMCF plan.

## **Relevant information from the risk management file**

This PMCF plan for [device short name] is defined based on the outputs of risk management file XXXX rev.Y approved on DD Month YYYY.

The relevant information from the risk management file to be specifically analyzed, followed-up, and evaluated are gathered in the following table.

Table 6: Relevant information from the risk management file

| **Relevant information from the risk management file** | **Risk management file section(s)** |
| --- | --- |
| Indicate the specific risks identified in the risk analysis to be monitored  |  |
| … |  |

/or

No relevant information from the risk management file needs to be considered in this PMCF plan.

# Evaluation of clinical data relating to equivalent or similar devices

PMCF activities of [device short name] also include the collection and evaluation of clinical data on the equivalent and similar devices described in the next table.

The PMCF methods and procedures applied for this evaluation are the same as the general procedures and methods C.1 and C.2 for [device short name]:

* Screening of scientific literature
* Screening of vigilance and recalls in publicly available databases

In addition, clinical data described in the current summary of safety and clinical performance (SSCP) for equivalent/similar devices will be evaluated in the PMCF evaluation report. Applicable to class III and implantable devices only

Table 7: Data on equivalent and similar devices

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Product Name****Manufacturer Name** | **Equivalent or similar device** | **Intended purpose** | **Intended users** | **Intended patient population** | **Medical condition** | **Indication** | **Reference to CER** |
|  |  |  |  |  |  |  | XXXX rev.Y, section Z |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

## Screening of scientific literature for equivalent or similar devices

### Objective

* Collect recent information relating to the state of the art
* Collect recent information to confirm the safety and performance acceptance criteria

### Description

A literature search will be implemented to detect the published and unpublished articles related to devices similar with or equivalent to [device short name].

The literature search methodology will be carried out in compliance with Section A5 of MEDDEV 2.7/1 rev.4. Research questions will be constructed using a PICO (Populations, Interventions, Comparators, Outcomes) process to justify the selection of relevant keywords.

The literature search will be applied in the following databases:

* Embase
* PubMed
* Cochrane Library
* EU Clinical Trials Register
* Clinicaltrials.gov
* XXXX

In the literature databases, the search queries will be defined using the selected keywords in a way to match with the language of each database used. The queries will have to incorporate the relevant search limitations (e.g., article type, language, as applicable).

The result of literature search will be a list of articles that will be screened in two stages:

* Level-1 screening is based on the titles and abstracts
* Level-2 screening is based on the full articles

The screening process consists of the review of each collected article to confirm if it should be included or excluded based on the inclusion/exclusion criteria.

The literature search will be implemented according to a literature search protocol that is defined based on the literature search protocol from the last CER. The results will be documented in a literature search report.

The result of the literature search will be extracted to ensure the characterization of safety and performance of similar and equivalent devices with the objective to perform a comparison with the safety and performance of [device short name].

The post-market clinical follow-up (PMCF) evaluation report for [device short name] will analyze and summarize the findings resulting from the literature search.

## Screening of vigilance and recalls in publicly available database for equivalent or similar devices

### Objective

* Collect recent information relating to the state of the art
* Collect recent information to confirm the safety and performance acceptance criteria

### Description

A vigilance / recall search will be implemented to detect the clinical risks (i.e., device problem, patient problems) related to devices similar with or equivalent to [device short name].

The vigilance / recall search methodology will be carried out using an approach similar to the literature search methodology. Research questions will be constructed using a PICO process to justify the selection of relevant keyword.

The vigilance / recall search will be applied in the following databases:

* FDA MAUDE
* FDA Medical Device Recalls
* FDA TPLC
* ANSM safety information
* Bfarm Field Corrective Actions
* MHRA Alerts, recalls and safety information: drugs and medical devices
* SwissMedic – FSCA and recall
* DAEN (Database of Adverse Event Notifications) - medical devices
* SARA (System for Australian Recall Actions)
* Canadian recalls and safety alerts
* XXXX

In the vigilance / recall databases, the search queries will be defined using the selected keywords in a way to match with the language of each database used. The queries will have to incorporate the relevant search limitations (e.g., search period).

The result of vigilance / recall searches will be a list of events that will be screened to determine if applicable to devices similar with or equivalent to [device short name].

The vigilance / recall search will be implemented according to a vigilance / recall search protocol that is defined based on the vigilance / recall search protocol from the last CER. The results will be documented in a vigilance / recall search report.

The post-market clinical follow-up (PMCF) evaluation report for [device short name] will analyze and summarize the findings resulting from the vigilance / recall search.

## Screening of summary of safety and clinical performance in EUDAMED

Only applicable to class III or implantable devices

### Objectives

* Collect recent information to confirm the safety and performance acceptance criteria

### Description

For MDR class III and implantable devices, manufacturers are required to make publicly available the summary of safety and clinical performance (SSCP) via EUDAMED. Until EUDAMED becomes fully functional, SSCPs may be found on the websites of manufacturers or in other public locations.

A search will be implemented to find the SSCPs of MDR devices similar or equivalent to [device short name] starting from EUDAMED and manufacturer websites.

The result of the search will be extracted to ensure the characterization of safety and performance of similar and equivalent devices with the objective to perform a comparison with the safety and performance of [device short name].

The post-market clinical follow-up (PMCF) evaluation report for [device short name] will analyze and summarize the findings resulting from the search of SSCPs.

# Reference to any applicable common specification(s), harmonized standard(s) or applicable guidance document(s)

| **Reference** | **Description** |
| --- | --- |
| **Common specifications** |
|  |  |
| **Harmonized standards** |
|  |  |
| **Guidance documents** |
| MDCG 2020-7 (April 2020) | Guidance on PMCF plan template |
| MDCG 2020-8 (April 2020) | Guidance on PMCF evaluation report template |
| XXXX |  |

# Estimated date of the PMCF evaluation report

Taking into account the timelines described in the summary table of PMCF activities in **Section C,** the overall timeline is:

* PMCF data collection period: from XXX to XXX
* PMCF data analysis period: from XXX to XXX
* PMCF evaluation report: XXX

# Appendix 1 – List of devices

| **Model number (UDI-DI)** | **Device description** | **EMDN code** | **Lifetime** | **Class and rule** |
| --- | --- | --- | --- | --- |
|  |  |  |  | Class X / Rule Y  |
|  |  |  |  | Class X / Rule Y  |
|  |  |  |  | Class X / Rule Y  |
|  |  |  |  | Class X / Rule Y  |
|  |  |  |  | Class X / Rule Y  |
|  |  |  |  | Class X / Rule Y  |
|  |  |  |  | Class X / Rule Y  |