**Periodic Safety Update Report**

For

[Device Name]

Manufacturer Name: [Manufacturer name]

Document Number: XXXX

Revision: XXXX

# Cover Page

Table 1: Cover page

|  |  |  |  |
| --- | --- | --- | --- |
| **1** | **Manufacturer information** | | |
| **a** | Manufacturer SRN: XXX | | |
| **b** | Manufacturer organization name: XXX | | |
| **c** | Contact’s first name: XXX | **e** | Contact’s last name: XXX |
| **d** | Email: XXX | **f** | Phone: XXX |
| **g** | Country: XXX | | |
| **h** | Street: XXX | **i** | Street number: XXX |
| **j** | Address complement: XXX | **k** | PO box: XXX |
| **l** | City name: XXX | **m** | Postal code: XXX |
| **2** | **Authorized representative information** | | |
| **a** | SRN: XXX | | |
| **b** | Authorized representative organization name: XXX | | |
| **c** | Contact’s first name: XXX | **e** | Contact’s last name: XXX |
| **d** | Email: XXX | **f** | Phone: XXX |
| **g** | Country: XXX | | |
| **h** | Street: XXX | **i** | Street number: XXX |
| **j** | Address complement: XXX | **k** | PO box: XXX |
| **l** | City name: XXX | **m** | Postal code: XXX |
| **3** | **Corresponding competent authority** | | |
| **a** | Name of National Competent Authority (NCA): XXX | | |
| **b** | EUDAMED number of NCA: XXX | | |
| **4** | **Notified Body** | | |
| **a** | NB organization name: XXX  NB number: XXX | | |
| **b** | Email: XXX | | |
| **5** | **Medical device information** | | |
| **a** | Leading device Basic UDI-DI / Eudamed DI(s): XXX | | |
| **b** | Other Basic UDI-DI(s) / Eudamed DI(s): XXX (See Appendix I) /OR See below | | |
| **c** | For each Basic UDI-DI / Eudamed DI, NB number and Certificate ID(s): XXX (See Appendix I) / OR   |  |  |  | | --- | --- | --- | | **Basic UDI-DI(s) / Eudamed DI(s)** | **NB Number** | **Certificate ID** | |  |  |  | |  |  |  | |  |  |  | | | |
| **6** | **PSUR Submission in Eudamed** | | |
| a | |  |  |  | | --- | --- | --- | | **Date of submission** | **Scheduled date** | **Timeliness** | | YYYY MM DD | YYYY MM DD | XXX Days | | | |
| b | **PSUR Reference Number:** XXXX | | |
| c | |  | | --- | | **Data Collection Period**: | | YYYY MM DD - YYYY MM DD | | | |
| d | **Version number:** XXX | | |
| 7 | **Upload the PSUR document:** XXX | | |

Items 6 and 7 are only applicable to class III devices

# Revision and Approval

## Approval

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

## Revision History

Table 2: Revision

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

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# Executive summary

This period safety update report (PSUR) is a standalone document that assesses the post-market data of [Device Name] (hereafter named [Device short name]) collected for the period from [start date] to [end date] and provides a general overview, assessment of results and conclusions of all analyzed post-market surveillance activities.

*Note: the data collection period meets the recommendations from MDCG 2022-21.*

Following the previous PSUR, all resulting actions have been completed, except the following:

* XXX describe the action and status.

Following the NB review of the previous PSUR, all questions have been addressed, except the following:

* XXX describe the action and status.

The PMS data collected in the current PSUR include: remove the bullet points that are not applicable and complete as necessary

* Vigilance
* Trends
* Field Safety Corrective Action (FSCA)
* Corrective Actions and Preventive Actions (CAPA)
* General Post-Market Clinical Follow-up (PMCF) procedures and methods with:
  + Feedback and complaints from users, distributors, and importers
  + Scientific literature and relevant specialist or technical literature
  + Public vigilance and clinical trial database
  + Publicly available information on similar devices:
    - Scientific literature
    - Public vigilance and recall database
    - Publicly available SSCP
    - Other (XXXX)
* Specific PMCF procedures and methods with:
  + Device registry
  + PMCF investigation
  + Patient/user survey
  + Other (XXXX)

In conclusion of the PMS data analysis:

* No new/emerging risk has been identified as compared to the last PSUR issued and the risk management file. Alternatively, identify the risk.
* The severity and likelihood of risks identified during the period covered by the PSUR have been compared to the threshold values defined in the risk management file and no risk exceeds the limits defined. Alternatively, identify the risk exceeding the threshold values and explain the impact on the B/R and if a notification to regulatory authorities has been performed.
* The trend of risks has been statistically analyzed to detect the significant increase trend. No statistically significant trend has been observed. Alternatively, identify the trends and explain the impact on the B/R and if a notification to regulatory authorities has been performed.
* Data on similar devices have been collected for comparison with [Device short name]. The results did not show any significant change in the state of the art and acceptable limits of safety and performance. Alternatively, identify any changes caused by data collected on similar devices.
* After analysis of data, no changes have been identified to the claimed benefits of [Device short name]. Identify any change to the benefits and describe the resulting actions.

Based on the analysis of the collected data, it is concluded that the benefit-risk profile of the device has not been /or has been adversely impacted and remains unchanged.

The result of the analysis of collected data did not emphasize any adverse impact on the benefit-risk profile of [Device short name] that remains unchanged)

* The summary of actions taken by the manufacturer

# Description of the devices covered by the PSUR and their intended use

## Scope of the PSUR

General regulatory information of devices covered by the PSUR are described in Appendix 1 – Devices in scope of the PSUR.

The following tables describe the devices that have been added and/or removed from the last PSUR and the summary of changes applied to the Basic UDI-DI(s).

Table 3: Addition and removal from the last PSUR

| **Basic UDI-DI / EUDAMED-DI** | **Device trade name** | **UDI-DI** |
| --- | --- | --- |
| **Devices added since the last PSUR** | | |
|  |  |  |
| **Devices removed since the last PSUR** | | |
|  |  |  |

Table 4: Changes since the last PSUR

| **Basic UDI-DI / EUDAMED-DI** | **Device changes since last PSUR** |
| --- | --- |
|  | * XXX |
|  | * XXX |

## Device history and regulatory status

The following table summarizes the marketing and regulatory status of devices in Europe.

Table 5: Device status in Europe

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade Name** | **Class** | **EU regulatory history (Date)** | | **Status** | |
| **First DoC** | **First EU/EC certificate** | **Marketed in the EU?** | **FSCA?** |
| ***Leading device*** | | | | | |
| [Device Name 1] | XX | DD-Mon-YYYY | DD-Mon-YYYY | on the market / no longer placed on the market | No ongoing FSCA /  Recalled / field safety corrective action |
| ***Other devices*** | | | | | |
| [Device Name 2] |  |  |  |  |  |
| [Device Name 3] |  |  |  |  |  |
| [Device Name 4] |  |  |  |  |  |
| [Device Name 5] |  |  |  |  |  |

## Intended use description

### Leading device: [Device Name 1]

#### Intended purpose

*Indicate the information as reported in the IFU*

#### Indications for use

*Indicate the information as reported in the IFU*

#### Contraindications

*Indicate the information as reported in the IFU*

#### Target populations

*Indicate the information as reported in the IFU*

### [Device Name 2]

#### Intended purpose

*Indicate the information as reported in the IFU*

#### Indications for use

*Indicate the information as reported in the IFU*

#### Contra-indications

*Indicate the information as reported in the IFU*

#### Target populations

*Indicate the information as reported in the IFU*

### [Device Name 3]

#### Intended purpose

*Indicate the information as reported in the IFU*

#### Indications for use

*Indicate the information as reported in the IFU*

#### Contraindications

*Indicate the information as reported in the IFU*

#### Target populations

*Indicate the information as reported in the IFU*

# Grouping of devices

Using the principles of MDCG 2022-21 coupled with the sampling methods of notified body described in MDCG 2019-13, [manufacturer name] (hereafter named [manufacturer short name]) reached the conclusion that grouping of devices described in **Appendix 1** – Devices in scope of the PSUR, is appropriate for the following reasons:

Select relevant and applicable reasons in the non-comprehensive list below.

* The PSUR contains class III devices under the same Basic UDI-DI,
* The PSUR contains class IIb devices under the same 4th level of EMDN code,
* The PSUR contains class IIa devices under the same MDN/MDA code,
* The PSUR contains several Basic UDI-DI for class III devices, several 4th level of EMDN code for class IIb devices several MDN/MDA codes for class IIa devices and/or several class I devices but they are all used together/in combination during the same procedure to achieve the intended performance and safety for the treatment/diagnosis of the patient.
* The PSUR contains devices of several classes, but they are all accessories intended to be coupled with [Device short name],
* The PSUR contains class III devices with different Basic UDI-DIs, but they are considered equivalent according to the MDCG 2020-5 as justified in the clinical evaluation report [DoC+Rev] / if the equivalence has not been claimed in the CER, include the equivalence table in appendix of this PSUR.
* The PMS report only contains class I devices that share the same intended use/indications for use and are based on a similar technology.
* The PSUR contains devices for which the grouping has been approved by NB (See [Doc number]

XXX Further justify the elements retained above with factual evidence and justify the benefits to report multiple devices in one PSUR or alternatively the disadvantages to report each device in separate PSURs.

Considering the characteristics of devices presented in **Appendix 1** – Devices in scope of the PSUR**,** the leading device has been selected with the highest classification and highest expected lifetime and is XXX. The leading device will drive the schedule of the PSUR such as data collection period covered, PSUR frequency, issuance timeline, PSUR reporting through EUDAMED, irrespective of the certification dates and classes of other devices.

# Volume of sales

The number of devices on the market has been evaluated based on the number of devices placed on the market or put into service OR units distributed OR active installed devices OR devices implanted OR *Other* A description/rationale should be provided

If a single Basic UDI-DI/Legacy device

Over the last 4 years (from [start date] to [end date]), a total of XXXX devices have been sold in EEA (including Turkey and North of Ireland) and XXXX devices have been sold worldwide as described in the following table with a yearly stratification.

OR

If a multiple Basic UDI-DIs/Legacy devices

Over the last 4 years (from [start date] to [end date]), a total of XXXX devices have been sold in EEA (including Turkey and North of Ireland) and XXXX devices have been sold worldwide. The following table provides the stratification of sales by Basic UDI-DI/Legacy Device with a yearly stratification.

Table 6: Sales

| **XXXX** Basic UDI-DI / Legacy Device / Model Number (as relevant) | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Regions** | **Total** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N2)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N3)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N4)** |
| EEA+TR + XI |  |  |  |  |  |
| Worldwide |  |  |  |  |  |

Duplicate the table per Basic UDI-DI (or Legacy devices when applicable) or device model (when relevant).

# Size and other characteristics of the population using the device

## Estimated size of the population using the device

For single use devices, the overall device usage should be the same as the number of sales above.

The products are single use devices, and their estimated usage is the same as the number of sales. Over the last four years (from [start date] to [end date]), XXXX devices have been sold in EU (including EEA, TR and XI) and XXXX in the rest of world. Hence the estimated mean usage is XXX in EU and XXX in the rest of world.

OR

For reusable devices, the overall device usage should be evaluated based on the sales multiplied with the number of uses per day / week / month extrapolated over a year. This estimation can be based on user feedback, clinical literature, or other means but should be justified.

The devices are reusable, and each device is estimated to be used X times over a year. The estimated usage per year has been determined considering XXXXX.

Over the last four years (from [start date] to [end date]), XXXX devices have been sold in EU (including EEA, TR and XI) and XXXX in the rest of world. Hence the estimated mean usage is XXX in EU and XXX in the rest of world. The following table provides the estimated usage based on the annual sales with a yearly stratification.

If multiple Basic UDI-DI/Legacy devices, the data shall be stratified by Basic UDI-DI/Legacy devices

Table 7: Estimated size of the population

| **Estimated size of population using the device** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Regions** | **Total** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N2)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N3)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N4)** |
| EEA+TR + XI |  |  |  |  |  |
| Worldwide |  |  |  |  |  |

## Characteristics of the population using the device

Considering the indications for use statement and targeted patient population as specified in the IFU, no claims for a use in a specific patient population have been identified. No specific monitoring of patient characteristics has been evaluated required in this PSUR.

OR

XXXX

1. Identify the patient characteristics identified in the IFU: draft a paragraph to identify the critical characteristics of the population using the device (e.g., multiple indications, pediatric/adult, male/female, etc.)
2. Justify the quantitative extrapolation for the patient characteristics: when it is possible to stratify the device use per indication/patient population, the table below must be completed (a rationale needs to be included if impossible). The quantitative data on the population characteristics using the device can be extrapolated per indication/patient population
3. Apply the extrapolation to the estimated number of uses and complete the table below.

If multiple Basic UDI-DI/Legacy devices, the data shall be stratified by Basic UDI-DI/Legacy devices.

Table 8: Characteristics X of the population

| **Characteristic X of population using the device** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Regions** | **Total** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N2)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N3)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N4)** |
| EEA+TR + XI |  |  |  |  |  |
| Worldwide |  |  |  |  |  |

Table 9: Characteristics Y of the population

| **Characteristic Y of population using the device** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Regions** | **Total** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N2)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N3)** | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N4)** |
| EEA+TR + XI |  |  |  |  |  |
| Worldwide |  |  |  |  |  |

# Post-market surveillance : vigilance and CAPA information

## Information concerning serious incidents

### Serious incidents per device problem

The following table describes the serious incident reported per device problem as described in the IMDRF Adverse Event – Medical Device Problem Code and per region.

Present the data in the following table per Basic UDI-DI (or Legacy devices when applicable) or device model when relevant.

Table 10: Serious incidents per IMDRF Adverse Events - medical device problem code

| **XXXX** Basic UDI-DI / Legacy Device / Model Number (as relevant) | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IMDRF Adverse Event - Medical Device Problem code (Annex A) and term by region** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N2)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N3)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N4)** | |
| **N** | **%** | **N** | **%** | **N** | **%** | **N** | **%** |
| EEA+TR+NI | AYYYYYY |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |
| EEA+TR+NI | AYYYYYY |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |

Link to the code:

<https://www.imdrf.org/working-groups/adverse-event-terminology/annex-medical-device-problem>

The TOP 5 of most frequent medical device problems reported over the last 4 years in EU are XX (%), XX (%), XX (%), XX (%) and XX (%).

Trends (Optional)

Recommendation to analyze the trends: you can use the LEX Excel spreadsheet: **LEX-TOOL-PMS-001 - Trend Analysis.**

As described in the PMS plan (see **Section 4.2**), the curve slops of trendlines have been evaluated for the incident rates reported year by year for each IMDRF Annex A codes identified in **Table 10**. No significant trends beyond X% (acceptance criteria to be indicated per PMS plan: 5%/10%) have been identified (See **Appendix 4** – Curve slops).

/OR, The following significant trends beyond X% have been identified with the identification of corresponding corrective action(s):

* XXXX identification of the trend

YYYY Identification of corresponding corrective action

* XXXX identification of the trend

YYYY Identification of corresponding corrective action

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

Comparison with threshold values

In addition, the severity and likelihood of risks identified have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the thresholds values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX (describe the risk, the update necessary in the risk management file)

### Serious incidents per finding of the investigation

The following table describes the serious incident reported per finding of investigation as described in the IMDRF Adverse Event – Investigation Findings Code and per region.

Present the data in the following table per Basic UDI-DI (or Legacy devices when applicable) or device model when relevant.

Table 11: Serious incidents per IMDRF Adverse Events – investigation findings code

| **XXXX** Basic UDI-DI / Legacy Device / Model Number (as relevant) | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IMDRF Adverse Event - Investigation Findings (Annex C) code and term by region** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N2)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N3)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N4)** | |
| **N** | **%** | **N** | **%** | **N** | **%** | **N** | **%** |
| EEA+TR+NI | CYYYYYY |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |
| EEA+TR+NI | CYYYYYY |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |

Link to the code: <https://www.imdrf.org/working-groups/adverse-event-terminology/annex-c-cause-investigation-investigation-findings>

The TOP 5 of most frequent investigation findings reported over the last 4 years in EU are XX (%), XX (%), XX (%), XX (%) and XX (%).

Trends (Optional)

Recommendation to analyze the trends: you can use the LEX Excel spreadsheet: **LEX-TOOL-PMS-001 - Trend Analysis.**

As described in the PMS plan (see **Section 4.2**), the curve slops of trendlines have been evaluated for the incident rates reported year by year for each IMDRF Annex C codes identified in **Table 11**. No significant trends beyond X% (acceptance criteria to be indicated per PMS plan: 5%/10%) have been identified (See **Appendix 4** – Curve slops).

/OR, The following significant trends beyond X% have been identified with the identification of corresponding corrective action(s):

* XXXX identification of the trend

YYYY Identification of corresponding corrective action

* XXXX identification of the trend

YYYY Identification of corresponding corrective action

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

Comparison with threshold values

In addition, the severity and likelihood of risks identified have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the thresholds values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX (describe the risk, the update necessary in the risk management file)

### Serious incidents per health impact

The following table describes the serious incident reported per health impact as described in the IMDRF Adverse Event Health Impact Code and per region.

Present the data in the following table per Basic UDI-DI (or Legacy devices when applicable) or device model when relevant.

Table 12: Serious incidents per IMDRF Adverse Events – health impact code

| **XXXX** Basic UDI-DI / Legacy Device / Model Number (as relevant) | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IMDRF Adverse Event Health Impact (Annex F) code and term by region** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N2)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N3)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N4)** | |
| **N** | **%** | **N** | **%** | **N** | **%** | **N** | **%** |
| EEA+TR+NI | FYYYYYY |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |
| EEA+TR+NI | FYYYYYY |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |

Link to the code: <https://www.imdrf.org/working-groups/adverse-event-terminology/annex-f-health-effects-health-impact>

The TOP 5 of most frequent health impact reported over the last 4 years in EU are XX (%), XX (%), XX (%), XX (%) and XX (%).

Trends (Optional)

Recommendation to analyze the trends: you can use the LEX Excel spreadsheet: **LEX-TOOL-PMS-001 - Trend Analysis.**

As described in the PMS plan (see **Section 4.2**), the curve slops of trendlines have been evaluated for the incident rates reported year by year for each IMDRF Annex F codes identified in **Table 12**. No significant trends beyond X% (acceptance criteria to be indicated per PMS plan: 5%/10%) have been identified (See **Appendix 4** – Curve slops).

/OR, The following significant trends beyond X% have been identified with the identification of corresponding corrective action(s):

* XXXX identification of the trend

YYYY Identification of corresponding corrective action

* XXXX identification of the trend

YYYY Identification of corresponding corrective action

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

Comparison with threshold values

In addition, the severity and likelihood of risks identified have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the thresholds values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX (describe the risk, the update necessary in the risk management file)

## Information from trend reporting

Trend analysis has been performed on non-serious incidents and known undesirable side-effects as described in the device labeling.

### Non-serious device problem

The following table describes the non-serious device problem reported for the last 4 years.

Table 13: Non-serious incidents per IMDRF Adverse Events - medical device problem code

| **XXXX** Basic UDI-DI / Legacy Device / Model Number (as relevant) | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IMDRF Adverse Event - Medical Device Problem code (Annex A) and term by region** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N2)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N3)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N4)** | |
| **N** | **%** | **N** | **%** | **N** | **%** | **N** | **%** |
| EEA+TR+NI | AYYYYYY |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |
| EEA+TR+NI | AYYYYYY |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |

Link to the code:

<https://www.imdrf.org/working-groups/adverse-event-terminology/annex-medical-device-problem>

The TOP 5 of most frequent medical device problems reported over the last 4 years in EU are XX (%), XX (%), XX (%), XX (%) and XX (%).

Trends (Optional)

Recommendation to analyze the trends: you can use the LEX Excel spreadsheet: **LEX-TOOL-PMS-001 - Trend Analysis.**

As described in the PMS plan (see **Section 4.2**), the curve slops of trendlines have been evaluated for the incident rates reported year by year for each IMDRF Annex A codes identified in **Table 13**. No significant trends beyond X% (acceptance criteria to be indicated per PMS plan: 5%/10%) have been identified (See **Appendix 4** – Curve slops).

/OR, The following significant trends beyond X% have been identified with the identification of corresponding corrective action(s):

* XXXX identification of the trend

YYYY Identification of corresponding corrective action

* XXXX identification of the trend

YYYY Identification of corresponding corrective action

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

Comparison with threshold values

In addition, the severity and likelihood of risks identified have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the thresholds values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX (describe the risk, the update necessary in the risk management file)

### Known undersirable side-effects

The following table describes the known undesirable side-effects reported for the last 4 years.

Present the data in the following table per Basic UDI-DI (or Legacy devices when applicable) or device model when relevant.

Table 14: Serious incidents per IMDRF Adverse Events – health impact code

| **XXXX** Basic UDI-DI / Legacy Device / Model Number (as relevant) | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IMDRF Adverse Event Health Impact (Annex F) code and term by region** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N2)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N3)** | | **From: DD/MM/YYYY**  **To: DD/MM/YYYY**  **(N4)** | |
| **N** | **%** | **N** | **%** | **N** | **%** | **N** | **%** |
| EEA+TR+NI | FYYYYYY |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |
| EEA+TR+NI | FYYYYYY |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |

Link to the code: <https://www.imdrf.org/working-groups/adverse-event-terminology/annex-f-health-effects-health-impact>

The TOP 5 of most frequent known side-effects reported over the last 4 years in EU are XX (%), XX (%), XX (%), XX (%) and XX (%).

Trends (Optional)

Recommendation to analyze the trends: you can use the LEX Excel spreadsheet: **LEX-TOOL-PMS-001 - Trend Analysis.**

As described in the PMS plan (see **Section 4.2**), the curve slops of trendlines have been evaluated for the incident rates reported year by year for each IMDRF Annex F codes identified in **Table 14**. No significant trends beyond X% (acceptance criteria to be indicated per PMS plan: 5%/10%) have been identified (See **Appendix 4** – Curve slops).

/OR, The following significant trends beyond X% have been identified with the identification of corresponding corrective action(s):

* XXXX identification of the trend

YYYY Identification of corresponding corrective action

* XXXX identification of the trend

YYYY Identification of corresponding corrective action

Comparison with threshold values

In addition, the severity and likelihood of risks identified have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the thresholds values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX (describe the risk, the update necessary in the risk management file)

## Information from field safety corrective actions (FSCA)

No FSCA has been implemented for the period from [start date] to [end date].

OR

The following table describes the FSCA implemented for the period from [start date] to [end date].

*Table 15: Field Safety Corrective Actions*

| **Type of action** | **Issuing date** | **Scope of the FSCA** | **Status of the FSCA** | **Manufacturer Reference Number** | **Rationale and description of action taken** | **Impacted Regions** |
| --- | --- | --- | --- | --- | --- | --- |
| Recall, FSN,… | XX/MM/YYYY |  | in process, finalized |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

As compared to the previous [Doc type]: remove the non-applicable items; customize as necessary

* no new field safety issue has been initiated,
* X FSCA has/have been initiated ([indicate the reference]),
* X FSCAs has/have been finalized ([indicate the reference]),
* X FSCA is/are still ongoing ([indicate the reference]).

XXXX [Include an overall summary]

## Preventive and / or corrective actions (CAPA)

A review of all CAPA generated and held by [manufacturer short name] for the corrective or preventive improvement of [Device short name] during the period from [start date] to [end date], has been conducted. No CAPA has been initiated / OR The summary of results is reported in the following table.

*Table 16: CAPA*

| **Type of action** | **Initiation date** | **Scope of the CAPA** | **Status of the CAPA** | **Manufacturer Reference Number** | **CAPA description** | **Root cause** | **Effectiveness of the CAPA if closed** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| CA | XX/MM/YYYY |  | in process, finalized |  |  | **DXXXX**  **WWWW terms** | Effectiveness verified, CAPA in progress |
| PA |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

Duplicate the table per Basic UDI-DI (or Legacy devices when applicable) or device model (when relevant).

Link to investigation conclusion: <https://www.imdrf.org/working-groups/adverse-event-terminology>

As compared to the previous [Doc type]: remove the non-applicable items; customize as necessary

* no new field safety issue has been initiated,
* X CAPAs has/have been initiated ([indicate the reference]),
* X CAPAs has/have been finalized ([indicate the reference]),
* X CAPA is/are still ongoing ([indicate the reference]).

XXXX [Include an overall summary]

# Post-market surveillance: information including general post-market clinical follow-up (PMCF) information

The following sections describe the results of general procedures and methods of PMCF activities as described in the PMCF Evaluation Report (See **Appendix 2** – Documents of reference)

## Feedback and complaints from users, distributors and importers

This section must be aligned with the PMCF Evaluation Report; If the data have been collected via the PMCF activities, refer to the Appendix 2; if the data have been collected through the PMS activities (i.e., as part of this PSUR) include the protocols/report(s) in appendices

No users, distributors or importers feedback have been collected in the PMCF activities for the period from [start date] to [end date].

*/OR*

According to the PMCF Evaluation Report (**Appendix 2** – Documents of reference), only the negative user, distributor, and importer feedback that are not reported in **Section 5,** have been reviewed. No feedback has been identified relevant to [Device short name] for the period from [start date] to [end date]. /OR For the period from from [start date] to [end date], the feedback relevant to [Device short name] are described in the following table.

Table 17: Medical device problems from economic operators and user feedback

| **Medical Device Problem[[1]](#footnote-1) / OR Internal Event Codes** | | **Occurrence**  **(n)** | **Rate\***  **(%)** | **Feedback ID number** | **Reason for inclusion** | **Reference to CAPA (if applicable)** |
| --- | --- | --- | --- | --- | --- | --- |
| **Code** | **Term** |
| AYYYYYY |  |  |  |  |  |  |
|  |  |
|  |  |
| AYYYYYY |  |  |  |  |  |  |
|  |  |
|  |  |
| AYYYYYY |  |  |  |  |  |  |
|  |  |
|  |  |
| AYYYYYY |  |  |  |  |  |  |
|  |  |
|  |  |

*\*For the period from [start date] to [end date], XXXX devices have been sold/used.*

In addition, the following feedback was not considered relevant to Medical Device Problems for [Device short name] and has not been considered in the analysis:

* #XXXX ID of feedback (XXX short description) – include a reason for exclusion
* #XXXX ID of feedback (XXX short description) – include a reason for exclusion
* #XXXX ID of feedback (XXX short description) – include a reason for exclusion

## Scientific literature review of relevant specialist or technical literature

This section must be aligned with the PMCF Evaluation Report; If the data have been collected via the PMCF activities, refer to the Appendix 2; if the data have been collected through the PMS activities (i.e., as part of this PSUR) include the protocols/report(s) in appendices

A literature search that supports the safety and performance of [Device short name], has been conducted for the period from [start date] to [end date], as documented in the PMCF Evaluation Report (See **Appendix 2** – Documents of reference).

The following databases have been searched using a keyword strategy defined via a PICO approach:

Table 18: Scientific literature on subject device

| **Database** | **Total number of results screened** | **Total number of articles included** |
| --- | --- | --- |
| Embase |  |  |
| PubMed |  |  |
| Cochrane Library |  |  |
| NICE |  |  |
| Other |  |  |

No article has been identified related to [Device short name].

/OR

A total of XX articles have been included (See **Appendix 3** – References of articles) with XX patients (from X to Y years old, X males/Y females) treated with [Device short name].

Stratify the data as necessary to cover the complete intended use characteristics (such as, indication 1, indication 2, male/female, adult/pediatric, etc., as necessary)

XX articles report clinical data on case-reports/case-series (XX patients), XX articles report off-label clinical data (XX patients), and XX articles report on-label clinical data (XX patients).

Each article has been summarized and appraised in the PMCF Evaluation Report (see **Appendix 2** – Documents of reference) and the following table presents the overall results including the key critical outcome parameters evaluated to support the safety and performance of [Device short name], the additional outcome parameters discussed in the literature, and the adverse effects reported.

Table 19: Results of the literature on the subject device

| **Articles** | **Key Critical Outcome Parameters** | **Additional Outcome Parameters** | **Clinical Risks (e.g., adverse effects, side-effects)** |
| --- | --- | --- | --- |
| **On-label use** | | | |
| XXX et al (YYYY)X | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result |
| **On-label case reports / case series** | | | |
| XXX et al (YYYY)X | N/A – safety and performance outcome parameters are not monitored as the quantity of patients is not sufficient to statistically discuss the results. | | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result |
| **Off-label use** | | | |
| XXX et al (YYYY)X | N/A – safety and performance outcome parameters are not monitored for the off-label uses of [Device short name] as they do not represent the intended use of the device. | | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result |

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

Comparison with threshold values

In addition, the severity and likelihood of risks identified have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the thresholds values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX (describe the risk, the update necessary in the risk management file)

Misuse/off-label use

No systematic off-label use has been found in the new articles identified through the literature search implemented.

/OR

Though off-label uses of [Device short name] have been identified, no systematic off-label use has been found in the new articles identified through the literature search implemented.

/OR

As part of the off-label uses of [Device short name], systematic off-label uses or misuses have been identified for the following indications:

* XXX Identify the indications and the reference to the articles

Identify how the systematic off label use is managed: design change (e.g., extension of indication), CAPA (additional precautions, warning, contraindications), continue the monitoring in the PMCF activities), etc.

* XXX

Benefits

Discuss the benefits achieved/newly identified considering the key criteria of safety and performance

[Device short name] benefits considering the key critical safety and performance outcome parameters have been reviewed and the results meet the acceptance criteria based on SOTA, defined in the current clinical evaluation report.

/OR

[Device short name] benefits considering the key critical safety and performance outcome parameters have been reviewed and the following findings have been found in comparison to the acceptance criteria based on SOTA, defined in the current clinical evaluation report.

* XXXX describe the results for the subject device that do not meet the acceptance criteria and provide a rationale

## Public databases and /or registry data

This section must be aligned with the PMCF Evaluation Report

### Public vigilance databases

This section must be aligned with the PMCF Evaluation Report; If the data have been collected via the PMCF activities, refer to the Appendix 2; if the data have been collected through the PMS activities (i.e., as part of this PSUR) include the protocols/report(s) in appendices

As documented in the PMCF Evaluation Report (see **Appendix 2** – Documents of reference), a review of publicly available vigilance databases has been implemented for the period from [start date] to [end date] to collect safety information on [Device short name] that can have been directly reported to regulatory authorities.

Public Vigilance databases have been questioned using keywords relevant to [Device short name]. The following tables summarize the number of relevant results obtained and the risk and occurrence of problems retrieved in the publicly available vigilance databases.

*Table 20: Vigilance on subject device*

| **PMS Database** | **Vigilance (n)** | | | **FSCA (n)** |
| --- | --- | --- | --- | --- |
| **Device-related** | **Patient-related** | **Death** |
| 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 | - | - | - |  |
| EUDAMED | - | - | - | - |
| **TOTAL** |  |  |  |  |

No vigilance or recall related to [Device short name] has been identified.

/OR

A total of X vigilance and X recalls have been found relevant to [Device short name]. The corresponding clinical risks identified are described in the following table.

*Table 21: Risks from vigilance database on subject device*

| **Event Types** | **Event reported** | **Occurrence reported** |
| --- | --- | --- |
| Device-related risks (device problem) |  |  |
|  |  |
|  |  |
|  |  |
| Patient-related risks (patient harm) |  |  |
|  |  |
|  |  |
|  |  |

IMDRF codes can be used

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

Comparison with threshold values

In addition, the severity and likelihood of risks identified have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the thresholds values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX (describe the risk, the update necessary in the risk management file)

### Public registry data

This section must be aligned with the PMCF Evaluation Report; If the data have been collected via the PMCF activities, refer to the Appendix 2; if the data have been collected through the PMS activities (i.e., as part of this PSUR) include the protocols/report(s) in appendices

As described in the PMCF Evaluation Report (see **Appendix 2** – Documents of reference), the following registers of clinical trials have been consulted to collect clinical safety and performance data on [Device short name] for the period from [start date] to [end date].

The following databases have been questioned using a keyword strategy defined via a PICO approach:

*Table 22: Clinical trials on subject device*

| **Database** | **Total number of results screened** | **Total number of trials included** |
| --- | --- | --- |
| ClinicalTrials.gov |  |  |
| EU Clinical Trial |  |  |
| WHO |  |  |

No clinical trial has been identified related to [Device short name].

/OR

A total of XX clinical trials have been included (See **Appendix 3** – References of articles) with XX clinical trials posted without results. Clinical trials with reported results involve XX patients (from X to Y years old, X males/Y females) treated with [Device short name]. Stratify the data as necessary to cover the complete intended use characteristics (such as, indication 1, indication 2, male/female, adult/pediatric, etc., as necessary)

XX clinical trials report data on case-reports/case-series (XX patients), XX clinical trials report off-label data (XX patients) and XX clinical trials report on-label data (XX patients).

Each clinical trial has been summarized in the PMCF Evaluation Report (See **Appendix 2** – Documents of reference) and the following table presents the overall results considering the key critical outcome parameters evaluated critical to support the safety and performance of [Device short name], the additional outcome parameters discussed in the literature and the adverse effects reported.

Table 23: Results of clinical trials on the subject device

| **Articles** | **Key critical Outcome Parameters** | **Additional Outcome Parameters** | **Clinical Risks (e.g., adverse effects, side-effects)** |
| --- | --- | --- | --- |
| **On-label use** | | | |
| XXX et al (YYYY)X | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result |
| **On-label case reports / case series** | | | |
| XXX et al (YYYY)X | N/A – safety and performance outcome parameters are not monitored as the quantity of patients is not sufficient to statistically discuss the results. | | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result |
| **Off-label use** | | | |
| XXX et al (YYYY)X | N/A – safety and performance outcome parameters are not monitored for the off-label uses of [Device short name] as they do not represent the intended use of the device. | | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result |

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

Comparison with threshold values

In addition, the severity and likelihood of risks identified have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the thresholds values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX (describe the risk, the update necessary in the risk management file)

Misuse/off-label use

No systematic off-label use has been found in the new articles identified through the literature search implemented.

/OR

Though off-label uses of [Device short name] have been identified, no systematic off-label use has been found in the new articles identified through the literature search implemented.

/OR

As part of the off-label uses of [Device short name], systematic off-label uses or misuses have been identified for the following indications:

* XXX Identify the indications and the reference to the articles

Identify how the systematic off label use is managed: design change (e.g., extension of indication), CAPA (additional precautions, warning, contraindications), continue the monitoring in the PMCF activities), etc.

* XXX

Benefits

Discuss the benefits achieved/newly identified considering the key criteria of safety and performance

[Device short name] benefits considering the key critical safety and performance outcome parameters have been reviewed and the results meet the acceptance criteria based on SOTA, defined in the current clinical evaluation report.

/OR

[Device short name] benefits considering the key critical safety and performance outcome parameters have been reviewed and the following findings have been found in comparison to the acceptance criteria based on SOTA,

* XXXX describe the results for the subject device that do not meet the acceptance criteria and provide a rationale

## Publicly available information about similar medical devices

Devices similar to [Device short name] are:

* XXX manufactured by YYY,
* XXX manufactured by YYY,
* XXX manufactured by YYY.

Public sources of clinical data have been consulted to collect information on similar devices for comparison with [Device short name]. The results are described in the following sections.

### Scientific literature review

This section must be aligned with the PMCF Evaluation Report; If the data have been collected via the PMCF activities, refer to the Appendix 2; if the data have been collected through the PMS activities (i.e., as part of this PSUR) include the protocols/report(s) in appendices

A literature search on devices similar to [Device short name], has been conducted for the period from [start date] to [end date], and is documented in the PMCF Evaluation Report (**Appendix 2** – Documents of reference).

The following databases have been questioned using a keyword strategy defined via a PICO approach:

Table 24: Scientific literature on similar devices

| **Database** | **Total number of results screened** | **Total number of articles included** |
| --- | --- | --- |
| Embase |  |  |
| PubMed |  |  |
| Cochrane Library |  |  |
| NICE |  |  |
| Other |  |  |

No article has been identified related to devices similar to [Device short name].

/OR

A total of XX articles have been included (See **Appendix 3** – References of articles) with patients treated with devices similar to [Device short name]. *Note: off-label use, case reports or case series have not been included.*

Each article has been summarized in the PMCF Evaluation Report (see **Appendix 2** – Documents of reference) and the following table presents the overall results considering the key critical outcome parameters evaluated critical to support the safety and performance of [Device short name], and the adverse effects reported in the literature.

*Table 25: Results from literature on similar devices*

| **Articles** | **Similar Device Used** | **Key critical Outcome Parameters** | **Clinical Risks (e.g., adverse effects, side-effects)** |
| --- | --- | --- | --- |
| XXX et al (YYYY)X | XXXX | * XXX * XXX * XXX * *[Include the parameter (with lifetime if necessary) and the result]* | * XXX * XXX * XXX * *[Include the parameter (with lifetime if necessary) and the result]* |

The results reported in the last CER for the key critical outcome parameters that support the safety and performance of [Device short name], have been compared to the results obtained for similar devices for the period from from [start date] to [end date]

Results for [Device short name] are within the limits defined based on devices similar to [Device short name].

/OR

Results for [Device short name] are out of specifications defined based devices similar to [Device short name] for the following parameters and clinical risks:

* XXX Include a rationale that supports how the results are still acceptable (e.g., still within the limits defined in the current CER, the CAPA XXX has been initiated to address the problem, a specific PMCF procedure is in place to confirm B/R profile etc.)

### Public vigilance and recall databases

As documented in the PMCF Evaluation Report (**Appendix 2** – Documents of reference), a review of publicly available vigilance and recall databases has been implemented for the period from [start date] to [end date] to collect safety information on devices similar to [Device short name].

Public Vigilance and Recall databases have been questioned using keywords relevant to devices similar to [Device short name]. The following tables summarize the number of relevant results obtained and the risk and occurrence of problems retrieved in the publicly available vigilance and recall databases.

Table 26: Number of results of vigilance and recall databases for similar devices

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PMS Database** | **Vigilance (n)** | | | **FSCA (n)** |
| **Device-related** | **Patient-related** | **Death** |
| 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 | - | - | - |  |
| EUDAMED | - | - | - | - |
| **TOTAL** |  |  |  |  |

No vigilance or recall related to devices similar to [Device short name] has been identified.

/OR

A total of X vigilance and X recalls have been found relevant to devices similar to [Device short name]. The clinical risks (i.e., device problems, patient harms) identified for the period from [start date] to [end date], are described in the following table.

Table 27: Summary of results of vigilance and recall databases for similar devices

|  |  |  |  |
| --- | --- | --- | --- |
| **Event Types** | **Event type reported for similar devices** | **Occurrence reported with similar devices** | **Comment** |
| Device-related risks (device problem) | XXX |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| Patient-related risks (patient harm) | XXX |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

IMDRF codes can be used

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

### Publicly available SSCP in EUDAMED

As documented in the PMCF Evaluation Report (**Appendix 2** – Documents of reference), a review of publicly available summary of safety and clinical performance on [date of search] has been implemented to collect safety and performance information on devices similar to [Device short name].

The following table summarizes the relevant results obtained.

Table 28: SSCP information on similar devices

| **Similar Device Used** | **Type of clinical data** | **Reference to clinical data** | **Key critical Outcome Parameters** | **Clinical Risks (e.g., adverse effects, side-effects)** |
| --- | --- | --- | --- | --- |
| XXX | e.g., clinical investigation, PMCF registry, literature articles | XXX | * XXX * XXX * XXX * *[Include the parameter (with lifetime if necessary) and the result]* | * XXX * XXX * XXX * *[Include the parameter (with lifetime if necessary) and the result]* |

## Other data sources

N/A

Other general procedures of PMCF (e.g., RW data from electronic health records, digital health-monitoring devices) can be included; subsection shall be customized, as necessary. Make sure to indicate: the source document (e.g., PMCF Evaluation Report), a summary of data, a list of findings in comparison to the safety and performance of the subject device.

# Specific post-market clinical follow-up (PMCF) information

No specific post-market clinical follow-up method and procedure has been defined as justified in the PMS plan / PMCF plan (see **Appendix 2** – Documents of reference).

/OR

The following specific post-market clinical follow-up method and procedure has been defined.

### Device registry

This section must be aligned with the PMCF Evaluation Report; If the data have been collected via the PMCF activities, refer to the Appendix 2; if the data have been collected through the PMS activities (i.e., as part of this PSUR) include the protocols/report(s) in appendices

A public registry has been defined/questioned to collect data that supports the safety and performance of [Device short name]. The data analyzed covers the period from [start date] to [end date], as documented in the PMCF Evaluation Report (See **Appendix 2** – Documents of reference).

No new results have been collected for the period covered.

/OR

A total of XX patients (from X to Y years old, X males/Y females) has been treated with [Device short name]. Stratify the data as necessary to cover the complete intended use characteristics (such as, indication 1, indication 2, male/female, adult/pediatric, etc., as necessary)

The data have been summarized and appraised in the PMCF Evaluation Report (see **Appendix 2** – Documents of reference) and the following table presents the overall results considering the key critical outcome parameters evaluated critical to support the safety and performance of [Device short name], the additional outcome parameters and the clinical risks reported.

Table 29: Results of the registry

| **Registry** | **Key critical Outcome Parameters** | **Additional Outcome Parameters** | **Clinical Risks (e.g., adverse effects, side-effects)** |
| --- | --- | --- | --- |
| XXX | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result |

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

Comparison with threshold values

In addition, the severity and likelihood of risks identified have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the thresholds values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX (describe the risk, the update necessary in the risk management file)

Benefits

Discuss the benefits achieved/newly identified considering the key criteria of safety and performance

[Device short name] benefits considering the key critical safety and performance outcome parameters have been reviewed and the results meet the acceptance criteria based on SOTA, defined in the current clinical evaluation report.

/OR

[Device short name] benefits considering the key critical safety and performance outcome parameters have been reviewed and the following findings have been found in comparison to the acceptance criteria based on SOTA,

* XXXX describe the results for the subject device that do not meet the acceptance criteria and provide a rationale

### PMCF investigation

This section must be aligned with the PMCF Evaluation Report; If the data have been collected via the PMCF activities, refer to the Appendix 2; if the data have been collected through the PMS activities (i.e., as part of this PSUR) include the protocols/report(s) in appendices

A PMCF investigation has been initiated to collect data that supports the safety and performance of [Device short name]. The data analyzed covers the period from [start date] to [end date], as documented in the PMCF Evaluation Report (See **Appendix 2** – Documents of reference).

No new results have been collected for the period covered.

/OR

A total of XX patients (from X to Y years old, X males/Y females) has been treated with [Device short name]. Stratify the data as necessary to cover the complete intended use characteristics (such as, indication 1, indication 2, male/female, adult/pediatric, etc., as necessary)

The data have been summarized and appraised in the PMCF Evaluation Report (see **Appendix 2** – Documents of reference) and the following table presents the overall results considering the key critical outcome parameters evaluated critical to support the safety and performance of [Device short name], the additional outcome parameters and the clinical risks reported.

Table 30: Results of PMCF investigations

| **Registry** | **Key critical Outcome Parameters** | **Additional Outcome Parameters** | **Clinical Risks (e.g., adverse effects, side-effects)** |
| --- | --- | --- | --- |
| XXX | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result | * XXX * XXX * XXX * Include the parameter (with lifetime if necessary) and the result |

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

Comparison with threshold values

In addition, the severity and likelihood of risks identified have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the thresholds values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX (describe the risk, the update necessary in the risk management file)

Benefits

Discuss the benefits achieved/newly identified considering the key criteria of safety and performance

[Device short name] benefits considering the key critical safety and performance outcome parameters have been reviewed and the results meet the acceptance criteria based on SOTA, defined in the current clinical evaluation report.

/OR

[Device short name] benefits considering the key critical safety and performance outcome parameters have been reviewed and the following findings have been found in comparison to the acceptance criteria based on SOTA,

* XXXX describe the results for the subject device that do not meet the acceptance criteria and provide a rationale

### Surveys

This section must be aligned with the PMCF Evaluation Report; If the data have been collected via the PMCF activities, refer to the Appendix 2; if the data have been collected through the PMS activities (i.e., as part of this PSUR) include the protocols/report(s) in appendices

A survey has been defined and sent to users/patients to collect data that supports the safety and performance of [Device short name]. The data analyzed covers the period from [start date] to [end date], as documented in the PMCF Evaluation Report (See **Appendix 2** – Documents of reference).

No new results have been collected for the period covered.

/OR

A total of XX feedback from patients/users has been collected for the period covered. The data have been summarized and appraised in the PMCF Evaluation Report (see **Appendix 2** – Documents of reference) and the following table presents the overall results related to the safety of [Device short name].

Table 31: Results from surveys

| **Event Types** | **Event reported** |
| --- | --- |
| Device-related risks (device problem) |  |
|  |
|  |
|  |
| Patient-related risks (patient harm) |  |
|  |
|  |
|  |

IMDRF codes can be used

Identification of new risks

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). No new risks have been identified for evaluation in the risk management file.

OR

Risk management documents (see **Appendix 2** – Documents of reference) are updated, when necessary, with the results of post-market surveillance (i.e., last [Doc type]). The following new risks have been identified for evaluation in the risk management file:

* XXX
* XXX

### Other

NA

### Overall assessment of specific PMCF activities

Following the implementation of specific PMCF activities for the period from [start date] to [end date], the following findings have been observed:

* XXX Include an overall summary of main positive and negative findings of specific PMCF activities

In conclusion, the results did not affect the B/R profile of [Device short name] and confirmed the safety and performance of the device. Identify the S&P problems or how the B/R profile is affected with a justification.

# Summary of findings and conclusions of the PSUR

## Validity of the collected data

This [Doc type] has been established based on the following source documents:

Remove the bullet points that are not applicable and add the bullet points that may be missing

* **Sales data** (See **Appendix 2** – Documents of reference) indicate the source document or the appendix where the information can be found.

Limitations: no limitation has been identified /OR XXX e.g., reduced sales or usage of the device, known bias from feedback obtained or enrolment into a study

* **Economic operators/User feedback** (See **Appendix 2** – Documents of reference) indicate the source document or the appendix where the information can be found.

Limitations: no limitation has been identified /OR XXX e.g., reduced sales or usage of the device, known bias from feedback obtained or enrolment into a study

* **Vigilance data** (See **Appendix 2** – Documents of reference) indicate the source document or the appendix where the information can be found.

Limitations: no limitation has been identified /OR XXX e.g., reduced sales or usage of the device, known bias from feedback obtained or enrolment into a study

* **CAPA data** (See **Appendix 2** – Documents of reference) indicate the source document or the appendix where the information can be found.

Limitations: no limitation has been identified /OR XXX e.g., reduced sales or usage of the device, known bias from feedback obtained or enrolment into a study

* **FSCA data** (See **Appendix 2** – Documents of reference) indicate the source document or the appendix where the information can be found.

Limitations: no limitation has been identified /OR XXX e.g., reduced sales or usage of the device, known bias from feedback obtained or enrolment into a study

* **PMCF Evaluation Report** (See **Appendix 2** – Documents of reference) indicate the source document or the appendix where the information can be found.

Limitations: no limitation has been identified /OR XXX e.g., reduced sales or usage of the device, known bias from feedback obtained or enrolment into a study

* Other PMS activities to be included

In the PMS activities documented above, no validity data limitation has been identified that may impact the conclusions and the assessment of the overall benefit-risk profile.

/OR

The limitations of data validity identified during the PMS activities are minor and do not affect the conclusions and the assessment of the overall benefit-risk profile.

If a significant bias is identified, this should be explained in detail, and ultimately, the data should be discarded if necessary

## Overall conclusions from the analysis of the collected data

### Conclusions on risks identified

A thorough assessment of all PMS activities has been conducted for the period from [start date] to [end date] and no new or emerging risks have been identified / OR and the following new or emerging risks have been identified:

* XXX indicate the risks identified and describe the source(s), rate/occurrence, circumstances, specific indication/specific patient population, etc., as applicable; describe how the B/R profile is not affected

In addition, the severity and likelihood of risks identified in this [Doc type] have been compared to the corresponding threshold values described in the risk management file (see **Appendix 2** – Documents of reference). No risks exceed the threshold values estimated during the risk management activities / OR The following risks have been identified with a severity or likelihood exceeding the threshold of the risk management activities:

* XXX describe the risk, describe how the B/R profile is not affected

The performed analysis on known undesirable side-effects and non-serious incidents did not identify any statistical trends exceeding the threshold value of severity or likelihood as identified in the risk management file (see **Appendix 2** – Documents of reference) / OR identified statistical trends exceeding the threshold value of severity or likelihood as identified in the risk management file (see **Appendix 2** – Documents of reference) for the following risks:

* XXX describe the risk, describe how the B/R profile is not affected OR the trend report that needs to be submitted

Finally, no new risks have been identified for similar devices /OR Finally, the following new risks have been identified for similar devices and they have been considered in the risk management file of [Device short name]:

* XXX

The review of similar device risks for the period considered did not reveal any impact on the acceptability of risks for the subject device /OR did reveal an impact on the acceptability of risks for the subject device:

* XXX describe the risk, impact, and the associated action plan (e.g., CAPA, PMCF)

### Conclusions on benefits identified

[manufacturer short name] evaluated the possible changes in benefits for [Device short name] via the post-market activities such as technical literature, register of clinical trials or specific PMCF procedures and methods Include the relevant PMS activities for which the benefits are evaluated.

The results gathered regarding the overall clinical safety and performance criteria that support the clinical benefits of [Device short name] are consistent with the last PSUR and the clinical evaluation report. There is no decrease in benefits for the [Device short name].

/OR

The results gathered regarding the overall clinical safety and performance criteria that support the clinical benefits of [Device short name] are not consistent with the last PSUR and the clinical evaluation report for the following criteria:

* XXX

There is a decrease in benefits for the [Device short name]. Propose a justification.

### Overall conclusion

The result of the analysis of collected data did not emphasize any adverse impact on the benefit-risk profile of [Device short name] that remains unchanged.

/OR

The result of the analysis of collected data emphasized an adverse impact on the benefit-risk profile of [Device short name]. The resulting action plan is described in **Section 8.3** Include a summary of actions to justify the new B/R profile is acceptable.

## Actions taken by the manufacturer

Following this PSUR, [manufacturer short name] must implement the following actions for the next collection period:

Table 32: Resulting actions from the manufacturer

| Actions | Yes/No | Description |
| --- | --- | --- |
| Update the risk management file for newly identified or emerging risks and occurrences of poor performance. |  | XXXX  Identify any necessary CAPAXXXX (or design change XXXX) |
| Update the design and manufacturing information |  | XXXX  Identify any necessary CAPAXXXX (or design change XXXX) |
| Update the IFU or labelling |  | XXXX  Identify any necessary CAPAXXXX (or design change XXXX) |
| Update the clinical evaluation |  | XXXX  Identify any necessary CAPAXXXX (or design change XXXX) |
| Update the SSCP |  | XXXX  Identify any necessary CAPAXXXX (or design change XXXX) |
| Implement the following CAPA |  | XXXX  Identify any necessary CAPAXXXX (or design change XXXX) |
| Implement the following FSCA |  | XXXX  Identify any necessary CAPAXXXX (or design change XXXX) |
| Contribute to the PMS of other devices |  | XXXX  Identify any necessary CAPAXXXX (or design change XXXX) |
| Report trends to competent authorities |  | XXXX  Identify any necessary CAPAXXXX (or design change XXXX) |
| Update the technical documentation |  | XXXX  Identify any necessary CAPAXXXX (or design change XXXX) |

# Appendix 1 – Devices in scope of the PSUR

| **Basic UDI-DI / EUDAMED-DI** | **Device trade name** | **Device description** | **UDI-DI** | **EMDN code** | **MDN / MDA code** | **Class** | **Lifetime** | **Certificate number** | **NB number** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Leading device** | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |
| **Other devices** | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

# Appendix 2 – Documents of reference

| **Document type** | **Document number and revision** |
| --- | --- |
| PMS Plan |  |
| PMCF Plan |  |
| PMCF Evaluation report |  |
| Risk management file |  |
| *Other external documents used in this PSUR should be added as needed* |  |
|  |  |

# 

# Appendix 3 – References of articles

[Device short name]

**Similar devices**

**Clinical trials**

# Appendix 4 – Curve slops

# Appendix 5 – attach documents produced in the frame of this PMS PSUR

1. IMDRF Adverse Event Terminology Annex A – “Medical Device Problem” [↑](#footnote-ref-1)