



*SOP-PSUR-TL01-V01*  
*Template for PSUR*

Product/-type/-family:		Date of the report:	
Risk class:	IIa or IIb or III	Period of the PSUR:	
Contact information of the manufacturer	Contact information of the responsible person:		

*The PSUR must be updated at least every 2 years for class IIa products. For class IIb and III devices, the update must be made at least once a year.*



**Periodic Safety Update Report (PSUR)**  
**Summary of the results and conclusions of the analysed data**  
**based on the PMS plan**

**Table of Contents**

<b>1. INTRODUCTION .....</b>	<b>3</b>
<b>2. SAFETY MEASURES TAKEN DURING THE REPORTING INTERVAL.....</b>	<b>3</b>
2.1. CHANGES TO LABELING OR INFORMATION FOR THE USER/IFU .....	3
2.2. FIELD SAFETY CORRECTIVE ACTIONS (FSCA) .....	3
2.3. OTHERS .....	4
<b>3. ANALYSIS OF THE DATA .....</b>	<b>4</b>
3.1. DATA ANALYSED IN THE POST-MARKET-SURVEILLANCE .....	4
3.2. RISK ASSESSMENT.....	8
3.3. MEASURES .....	8
<b>4. PMCF RESULTS .....</b>	<b>8</b>
<b>5. DATA ON PRODUCT USE .....</b>	<b>8</b>
<b>6. CONCLUSIONS .....</b>	<b>9</b>
6.1. TREND DESCRIPTION .....	9
6.2. DO MODIFICATIONS NEED TO BE MADE TO THE TECHNICAL DOCUMENTATION? If so, WHICH ONES? .....	9
6.3. EVALUATION OF THE BENEFIT-RISK RATIO .....	9
<b>7. CHANGE LOG .....</b>	<b>9</b>



## 1. Introduction

*Short description of the product (name, composition, classification, intended use and user).*

In this PSUR, the applied PMS system, the PMS plan and the evaluation of the collected PMS information are in accordance with the EU Medical Device Regulation (MDR) 2017/745 Art. 83, 84, 85 and Annex III.

The PMS system and the PMS plan of [company] are summarized in SOP [XX] which describes:

- the proactive and systematic process used to collect all available information from the market
- the effective and appropriate methods and processes used to assess the collected data
- the procedures to fulfil the manufacturers obligations for post market surveillance as laid down in MDR articles 83, 84 and 85
- the suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management

## 2. Safety measures taken during the reporting interval

### 2.1. Changes to labeling or information for the user/IFU

Have there been any changes in the labelling or the IFU? Yes  No

If so, please briefly explain:

---

---

Reference document:

---

---

### 2.2. Field safety corrective actions (FSCA)

Have FSCAs been implemented? Yes  No

If so, please briefly explain:

---

---

Reference document:

---

---



### 2.3. Others

Were there other safety measures taken? Yes  No

If so, please briefly explain:

---

---

Reference document:

---

---

## 3. Analysis of the data

### 3.1. Data analysed in the post-market-surveillance

#### a) Complaints

Were there complaints? Yes  No  N/A

Total number of complaints:

---

Number of causes for complaints:

---

Cause for complaint	Number	New?		Increased frequency?	
Type 1		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Type 2		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Type 3		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Set complaints in relation to sales numbers:

*(if necessary, break down by modifications, countries, etc.)*

year	sold units	number of complaints

Was it necessary to take preventive or corrective actions? Yes  No  N/A

If so, please briefly explain:

---

---

Reference documents:

---

---

#### b) Feedback from the distributor channel

Has feedback regarding the product been documented? Yes  No  N/A



If so, please briefly explain:

---

---

Was it necessary to take preventive or corrective actions? Yes  No  N/A

If so, please briefly explain:

---

---

Reference documents:

---

---

**c) Evaluation of internal defect reports**

Has the product been referenced in internal error reports? Yes  No  N/A

If so, please briefly explain:

---

---

Was it necessary to take preventive or corrective actions? Yes  No  N/A

If so, please briefly explain:

---

---

Reference documents:

---

---

**d) Risks resulting from product changes**

Were there any risks arising from product changes? Yes  No  N/A

If so, please briefly explain:

---

---

Was it necessary to take preventive or corrective actions? Yes  No  N/A

If so, please briefly explain:

---

---

Reference documents:

---

---



**e) Literature search on clinical data**

Were there publications of clinical data (own product and equivalent products)?

Yes  No  N/A

Please insert the summary of the CER:

---

---

---

---

Was it necessary to take preventive or corrective actions?

Yes  No  N/A

If so, please briefly explain:

---

---

Reference documents:

---

---

**f) Incidents and evaluation of authority notifications (BfArM, MAUDE)**

Have incidents been reported for the medical device?

Yes  No  N/A

Number of incidents in total:

---

Number of root causes for incidents:

---

---

Description of incidents:

Incident	serious	non-serious	Number	New?		Increased frequency	
				Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Type 1	<input type="checkbox"/>	<input type="checkbox"/>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Type 2	<input type="checkbox"/>	<input type="checkbox"/>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Type 3	<input type="checkbox"/>	<input type="checkbox"/>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Have there been reports of recalls in the databases?

Yes  No  N/A

If so, please briefly explain:

---

---

---

---

Was it necessary to take preventive or corrective actions?

Yes  No  N/A

If so, please briefly explain:

---

---



Reference documents:

---

---

**g) Feedback from users (health professional or lay person)**

Do relevant data emerge from the feedback? Yes  No  N/A

If so, please briefly explain:

---

---

Was it necessary to take preventive or corrective actions? Yes  No  N/A

If so, please briefly explain:

---

---

Reference documents:

---

---

**h) Others**

Are there any other remarks on the product and equivalent products that have not been taken into account so far? Yes  No  N/A

If so, please briefly explain:

---

---

Was it necessary to take preventive or corrective actions? Yes  No  N/A

If so, please briefly explain:

---

---

Reference documents:

---

---



### 3.2. Risk assessment

Were there risks that required an update of the risk management? Yes  No

If yes, please briefly explain:

---

---

---

---

### 3.3. Measures

Were further measures to be taken? Yes  No

If yes, please briefly explain:

---

---

---

---

## 4. PMCF results

*Please briefly describe the main results.*

---

---

---

## 5. Data on product use

Estimated number of product users:

---

Frequency of product use:

*If practicable: Does the application take place in defined cycles (monthly, weekly?) or rather once only?) Please explain how this estimation is derived.*

---

---

Product user characteristics:

*e.g. age groups, clinical pictures or similar*

---

---

---





## 6. Conclusions

### 6.1. Trend description

*Compared to the previous PMS report, is there a significant increase in the frequency or severity of non-serious events or expected adverse events that resulted, could have resulted or could result in risks to the health or safety of patients, users or others?  
If so, then it is notifiable.*

---

---

---

---

### 6.2. Do modifications need to be made to the technical documentation? If so, which ones?

*Benefit-risk ratio of medical devices?  
Update of risk management necessary?  
Updating of the design, in the production or the instructions for use?  
Update of clinical evaluation necessary?*

---

---

---

---

### 6.3. Evaluation of the benefit-risk ratio

*Has the benefit-risk ratio changed?*

---

---

---

---

## 7. Change Log

Version	Reason for Change	Author	Effective date
1.0	New document		