Product/-type/-family:		Date of the report:	
Risk class:	I otherwise PSUR!	Period of the PMSR:	
Contact information of the manufacturer		Contact information of the responsible person:	

The PMSR shall be updated as necessary and made available to the responsible authority on request.

PMS-Report

Summary of the results and conclusions of the analysed data based on the PMS plan

Table of Contents

1. Introduction

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

In this PMS report, 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 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 ☐	No ☐	Yes ☐	No ☐
Type 2		Yes ☐	No ☐	Yes ☐	No ☐
Type 3		Yes ☐	No ☐	Yes ☐	No ☐

If available, set complaints in relation to sales numbers:

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	
Type 1	☐	☐		Yes ☐	No ☐	Yes ☐	No ☐
Type 2	☐	☐		Yes ☐	No ☐	Yes ☐	No ☐
Type 3	☐	☐		Yes ☐	No ☐	Yes ☐	No ☐

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. Conclusions

4.1. 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.

4.2. 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?

5. Change Log

Version	Reason for Change	Author	Effective date
1.0	New document		