Appendix 3 – Periodic Safety Update Report

[illegible]	
Product:	
Attendees:	

Data Summary:

PMS activities in PMS plan	Discussion about data
[illegible]	
Non-serious incidents [illegible]	
Trend reporting (data analysis)	
[illegible]	
Feedback and customer complaints	
[illegible]	

Commented [13A1]: Write in here brief information about the outcomes of the surveillance meeting.

[illegible]

Conclusions:

PMS activities	Conclusions:
Serious incidents and [illegible]	
Non-serious incidents [illegible]	
Trend reporting (data analysis)	
[illegible]	
Feedback and customer [illegible]	

Commented [13A2]: Write in there if there are any new actions [illegible]

Publicly available	

Corrective actions:

Corrective action	Record ID	

Overall conclusion

[name]

[signature]

Commented [13A3]: If there is a need for corrective action,

Commented [13A4]: Please include the record ID as registered in the Corrective and Preventive Action Request.

Commented [13A5]: E.g. found new adverse events, found new

Commented [13A6]: E.g. the medical device is safe for use,

Commented [13A7]: Please insert the month and year when

Commented [13A8]: It is mandatory to include the name of the

Commented [13A9]: Only necessary if document is in paper form.