Appendix 5 – Risk Management Review

[illegible]			
Risk Management Plan ID			
Medical Device ID			
[illegible]			
[illegible]	From [date] to [date]		
[illegible]	[name], [job title], team manager [name], [job title], team member		
[illegible]	[Yes/No]	Signature	
[illegible]			
[illegible]	[illegible]	[illegible]	Approved by
[illegible]			
Post-market surveillance report ID			
[illegible]			
[illegible]			
Actions and conclusion:			
[illegible]	[name], [job title]		

[job title]
[name]

_____
[signature]

Commented [13A1]: The data in these columns should be taken from the Risk Assessment Record.

Commented [13A2]: Please include the Risk ID from the Appendix 4 – FMEA Risk Assessment Record.

Commented [13A3]: Please include the data for the RPN from the Appendix 4 – FMEA Risk Assessment Record

Commented [13A4]: Acceptable/Not acceptable.

[illegible]

Commented [13A5]: If your medical device is class I please [illegible]

You can find templates for these documents in the ISO 13485 & MDR Integrated Documentation Toolkit folder "18_Post_Market_Surveillance".

Commented [13A6]: Please include the report ID from the Data Analysis Report.

You can find template for this document in the ISO 13485&MDR Integrated Documentation Toolkit folder "22_Data_Analysis".

Commented [13A7]: If performing Post-market surveillance or [illegible]

Commented [13A8]: Conclude here if the risk management [illegible]

[illegible]

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

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