Appendix 4 – Risk Management Review

Risk Management File ID:			
Risk Management Plan ID:			
Medical device ID:			
Risk assessment performed:	[redacted]		
Risk assessment team:	[redacted]		
Risk Management Plan was appropriately implemented:	[redacted]	Signature:	
Overall residual risks			
[redacted]	[redacted]	Approved by	
Production and post-production activities			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
Appropriateness of the methods confirmed by:	[redacted]		

[job title]
[name]

[signature]

Commented [AES1]: The data in these columns should be [redacted]

Commented [AES2]: Include the process name from the Risk [redacted]

Commented [AES3]: Include the information from the Risk [redacted]

Commented [AES4]: If your medical device is class I, include the Report ID from the Post-Market Surveillance Report.

[redacted]

Commented [AES5]: Include the report ID from the Data Analysis Report.

[redacted]

Commented [AES6]: If performing Post-market surveillance or [redacted]

Commented [AES7]: Conclude here if the risk management process has covered all phases of medical device lifecycle, if Risk [redacted]

Commented [AES8]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.

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