Appendix 1 – Risk Management Plan

Risk Management Plan ID		Medical Device ID	
[illegible]			
[illegible]			
Medical Device Lifecycle Stages			
[illegible]			
[illegible]			
Risk Acceptance Criteria			
[illegible]			
Verification Activities			
[illegible]			
Risk Management File ID			

[job title]
[name]

_____
[signature]

Commented [13A1]: If the organization uses electronic databases, then this Appendix is not needed, and data listed here can be stored in the database.

Commented [13A2]: Write a short description of the device: [illegible]

Commented [13A3]: Please include short description of the production process.

Commented [13A4]: Include information related to which risk assessment methodology is used and include short description of the methodology.

If you will use the 06.4_Appendix_4_FMEA_Risk_Assessment_Record_Integrated_EN, then write a reference to that document.

Commented [13A5]: Criteria for risk acceptability are derived from the organization's procedure for risk assessment.

If you will use the FMEA methodology and the 06.3_Appendix_3_Procedure_for_FMEA_Risk_Assessment_Integrated_EN document, then copy the table from section 3.5 in the document.

Commented [13A6]: For example: gathering and reviewing data from literature of the same device, or similar medical device.

Commented [13A7]: Verifying the effectiveness of risk control [illegible]

Commented [13A8]: The method or methods of obtaining post-[illegible]

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