Appendix 1 – Risk Management Plan

Risk Management Plan ID		Medical device ID	
Date of the Risk Management Plan			
Scope			
Risk management team			
Medical device description			
Medical device lifecycle stages			
Risk assessment methodology			
Severity			
Probability of occurrence			
Risk acceptance criteria			
Methods to evaluate overall residual risks			
Verification activities			
Benefit-risk analysis			
Criteria for benefits			
Magnitude of the benefit			
Frequency			

Commented [AES1]: If the organization uses electronic

Commented [AES2]: Write the scope of the Risk Management

Commented [AES3]: Write a short description of a device:

Commented [AES4]: Include short description of the

Commented [AES5]: Include information related to which risk

Commented [AES6]: The risk management team must define the level of severity for each medical device.

Commented [AES7]: You should choose the severity level

Commented [AES8]: The risk management team must define the level of probability of occurrence for each medical device.

Commented [AES9]: You should choose the probability of

Commented [AES10]: Criteria for risk acceptability are derived

Commented [AES11]: For example: gathering and reviewing

Commented [AES12]: Verifying the effectiveness of risk control measures can require the collection of clinical data, usability

Commented [AES13]: Choose the one applicable to your

Post-production information	
Method or methods of obtaining relevant post-production information	
Risk Management File ID	
Requirements to review the risk management activities	

Commented [AES14]: The method or methods of obtaining post-production information can be part of established Quality Management System procedures.

Commented [AES15]: Write the requirements for the circumstances under which you will conduct a review of the performed risk assessment.

[job title]
[name]

_____
[signature]

Commented [AES16]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.