

## Appendix 1 – Risk Management Plan

Risk Management Plan ID		Medical device ID	
Date of the Risk Management Plan			
Scope			
Risk management team	Name, position, email address Name, position, email address		
Medical device description	Medical device name		
	Model number		
	Accessories/attachments		
	Other identifiers		
Medical device lifecycle stages			
<b>Risk assessment methodology</b>			
Severity	1 - Negligible 2 - Moderate 3 - Significant 4 - Critical 5 - Catastrophic		
Probability of occurrence	1 - Rare 2 - Unlikely 3 - Possible 4 - Frequent 5 - Very frequent		
Risk acceptance criteria	Low risk, acceptable risk		
	Risk is low or acceptable without affecting the benefit risk analysis		
Methods to evaluate overall residual risks	High risk, unacceptable risk		
Verification activities			
<b>Benefit-risk analysis</b>			
Criteria for benefits			
Magnitude of the benefit	1 - Negligible 2 - Moderate 3 - Significant		
Frequency	1 - Rare 2 - Unlikely 3 - Possible		

**Commented [AES1]:** If the organization uses electronic devices, include the device ID.

**Commented [AES2]:** Write the scope of the Risk Management Plan.

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

**Commented [AES4]:** Include short description of the device.

**Commented [AES5]:** Include information related to which risk assessment methodology is used.

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

**Commented [AES7]:** You should choose the severity level for each medical device.

**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 occurrence for each medical device.

**Commented [AES10]:** Criteria for risk acceptability are derived from the risk management plan.

**Commented [AES11]:** For example: gathering and reviewing clinical data, usability testing, etc.

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

**Commented [AES13]:** Choose the one applicable to your device.

[organization name]

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]

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[signature]

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