

[organization name]

Appendix 2 – Risk Management File

Commented [AES1]: If the organization uses electronic

Risk Management File ID		Medical device ID	
Risk Management Plan ID			
Risk assessment methodology		Risk Assessment Record ID	
Risk assessment results			
Risk ID	Risk area	Risk assessment	
Risk control measures			
Description of the activity	Responsible person	Verification method	Responsible for completion
Intended use of the medical device			
Intended use of the medical device			
Benefit-risk analysis			
Risk ID	Benefit or safety issue	Responsible person	

Commented [AES2]: If you will use the Risk Assessment Record

Commented [AES3]: If you will use the Risk Assessment Record

Commented [AES4]: Acceptable / Not acceptable.

Commented [AES5]: If you will use the Risk Assessment Record

Date: [date]

[organization name]

[job title]

[name]

[signature]

Commented [AES6]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.