

[organization name]

Appendix 2 – Risk Management File

Risk ID		Risk Value		Risk Acceptance	
Verification Results		Residual Risk Acceptance			
Intended use					
Benefit-risk Analysis					
Risk ID					

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]: If you are using 06.4_Appendix_4_FMEA_Risk_Assessment_Record_Integrated_EN template, copy the Risk ID from there.

Commented [13A3]: If you are using FMEA methodology for risk assessment, please include the RPN (Risk Priority Number) as defined in column I of the 06.4_Appendix_4_FMEA_Risk_Assessment_Record_Integrated_EN document.

Commented [13A4]: Acceptable/Not acceptable. If you will use the FMEA methodology and the 06.3_Appendix_3_Procedure_for_FMEA_Risk_Assessment_Integrated_EN, use information included in the table in section 3.5 of the document.

Commented [13A5]: If you will use the FMEA methodology and the 06.3_Appendix_3_Procedure_for_FMEA_Risk_Assessment_Integrated_EN, use information included in the table in section 3.5 of the document.

[job title]

[name]

[signature]

Commented [13A6]: Only necessary if document is in paper form.

Date:

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