Appendix 1 – Design and Development File

Design and Development Project ID	
[illegible]	
Design and Development team leader:	
[illegible]	
Date of issuing project task:	
[illegible]	
Project deadline:	
[illegible]	
Product characteristics [illegible]	*
Statutory and regulatory requirements:	*
[illegible]	*
Potential consequences of failure due to nature of the product or service:	*
[illegible]	
Project phase	Reference documents
*	*
*	*
*	*
*	*
*	*
*	*
[illegible]	

[job title]
[name]

_____
[signature]

Commented [134851]: If organization uses electronic databases, then this Appendix is not needed, and data listed here can be stored in database.

Commented [134852]: For example, product characteristics [illegible]

Commented [134853]: For example, European Union Medical Device Regulation

Commented [134854]: For example, Council Directive [illegible]

Commented [134855]: For example, FMEA Risk Assessment Record No.3435

Commented [134856]: For example, definition of initial design

Commented [134857]: For example, Initial Design Document No.3435

Commented [134858]: For example, [illegible]

Commented [134859]: For example, Project Plan and Review No-3435

Commented [1348510]: [illegible]

Commented [1348511]: For example, [illegible]

Commented [1348512]: For example, testing the prototype No.3435.01

Commented [1348513]: For example, [illegible]

Commented [1348514]: For example, [illegible]

Commented [1348515]: For example, Change Review Record No.3435

Commented [1348516]: [illegible]

Commented [1348517]: For example, Design and Development Transfer Record No.3435

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