

[organization name]

## Appendix 1 – Design and Development File

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

Design and Development Project ID	
Design and Development team leader:	
Date of issuing project task:	
Project deadline:	
<b>Section 1: Design and Development</b>	
Product characteristics	*
Statutory and regulatory requirements:	*
Potential consequences of failure due to nature of the product or service:	*
<b>Section 2: Design and Development</b>	
Project phase	Reference documents
*	*
*	*
*	*
*	*
*	*
*	*

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

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

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

**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,

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

**Commented [1348510]:**

**Commented [1348511]:** For example,

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

**Commented [1348513]:** For example,

**Commented [1348514]:** For example,

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

**Commented [1348516]:**

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

[job title]

[name]

\_\_\_\_\_  
[signature]