

[organization name]

## Appendix 1 – Design and Development File

Design and Development Project ID	
Medical device ID	
Date of issuing project task:	
Project deadline:	
<b>Product characteristics and requirements</b>	
Statutory and regulatory	
Potential consequences of failure due	
<b>Design and development project</b>	

**Commented [13A1]:** If organization uses electronic databases, then this Appendix is not needed, and data listed here can be stored in database.

**Commented [13A2]:** For example, product characteristics are

**Commented [13A3]:** For example, European Union Medical Device Regulation

**Commented [13A4]:** For example, Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)

**Commented [13A5]:** For example, FMEA Risk Assessment Record No.3435

**Commented [13A6]:** For example, definition of initial design

**Commented [13A7]:** For example, Initial Design Document No.3435

**Commented [13A8]:** For example,

**Commented [13A9]:** For example,

**Commented [13A10]:**

**Commented [13A11]:** For example,

**Commented [13A12]:** For example, No.3435.01

**Commented [13A13]:** For example, No.3435.01

**Commented [13A14]:** For example,

**Commented [13A15]:** For example, Change Review Record No.3435

**Commented [13A16]:**

**Commented [13A17]:** For example, Design and Development Transfer Record No.3435

**Commented [13A18]:** Only necessary if document is in paper form.

[job title]

[name]

[signature]