Appendix 1 – Design and Development File

Design and development Project ID	
Medical device ID	
Design and development team leader:	
[illegible]	
[illegible]	
[illegible]	
[illegible]	
Inputs for design and development	
Product characteristics (Functional and performance requests):	
Statutory and regulatory requirements:	
[illegible]	
[illegible]	
Design and development project	
Project phase	[illegible]
[illegible]	

[job title]
[name]

[signature]

Commented [AES1]: If the organization uses electronic [illegible]

Commented [AES2]: For example, product characteristics are [illegible]

Commented [AES3]: For example, European Union Medical [illegible]

Commented [AES4]: For example, Council Directive [illegible]

Commented [AES5]: For example, Risk Assessment Record No.3435

Commented [AES6]: For example, definition of initial design.

Commented [AES7]: For example, Initial Design Document No.3435.

Commented [AES8]: For example, developing a project plan.

Commented [AES9]: For example, Project Plan and Review No-3435.

Commented [AES10]: Designing product No.3435

Commented [AES11]: For example, drawing No.3435

Commented [AES12]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.