

Design Development File	Project xxx
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#	Design Control Deliverables
1	Design and Development Plan
2	Regulatory Pathway
3	List of applied standards and regulations
4	Design Input
5	Design Input Review Report
6	Design Output Documents
7	Design V&V Plan
8	Design Verification Protocols/Reports
9	Biocompatibility Testing
10	Packaging and labelling
11	Sterilisation Validation
12	Shelf-Life Testing Plan/Report
13	Design Verification Review Report
14	Design Validation Plan/Report
15	Design V&V Report
16	Clinical Evidence
17	Design Transfer
18	Risk Management & Usability File
19	Final Design Review Report
20	Logbook of Changes

Approval	<i>name / date / signature</i>
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