Technical Documentation ("Technical File") requirements:

1	Introduction to the device and any variants	
2	Description of intended use	F2
3	Brief description	F1
4	List of accessories	F4
5	Location of responsibilities e.g. design, production, sterilisation, EU authorised representative for these devices	J1
6	Details of significant subcontractors as applicable e.g. software, sterilisation, manufacture, packaging including details of any Quality system certifications they hold (e.g. copies of certificates including scope of certification)	Y19 B5 B3
7	Solutions adopted to fulfil the Essential Requirements (e.g. ER checklist), including standards used and cross reference to any supporting evidence	C1
8	Design input specification	Y2
9	Risk Analysis document for the system	E
10	Detailed test results for device verification i.e. evidence that the system meets its own specification. Also, detailed results for safety and EMC testing. If testing was performed by third party laboratories then please also provide copies of test certificates and report.	Y15 Y18 D5 Z1 Z2
11	Details of Clinical Trials and/or compilation of scientific literature together with a critical review of the literature and how it relates to this system (see Annex X of MDD and MEDDEV 2.7.1).	H3 L1
12	Copies of the instructions for use and the artwork for the labelling.	F5 F6
13	Details of any medicinal substance present or animal tissues.	Z8 Z10
14	Classification rationale including the Annex IX rule numbers used for these devices	D1
15	Copy of the Declaration of Conformity for the devices	B1
16	Copy of the document where the life time of the product is defined (see ER 4)	G4
17	Copy of the procedure for the generation of a "Technical File"	
18	Copy of the procedure for new product design	Y2
19	Copy of the risk management procedure	E10
20	Details of the applicability of the Machinery Directive – i.e. is the device considered a machine in the eyes of this Directive?	D9