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Section	Description	Ref MDD	Document	Status	N/A	Done
	Technical File					
	Index to Technical Documentation		Index to Technical Documentation			Y
	CD Amendment Controls		AMCOM			
A	Reference to documents		Reference to Documents			Y
B	EC Declaration of Conformance	AnII /V/VI	ECDEC		*	
B1	Notified Body Certification					
C	Essential Requirements	art 3	ERCHVN			Y
C1	EN Standards	AnII 3.2c	Reference to EN Standards			Y
D	Classification Rationale Flow Chart	AnIX art II	Clasrat			
D1	EMC Rationale		EMC			
E	Risk Analysis	AnII 3.2c	RAISKAN			
E1	Risk Analysis EN1441		RARCL			
F	Description device w/drawing	AnII3.1	DDES			
F1	Accessories	AnII 3.1	Access			
F2	Instructions	ER 13	INSTRUCT			
F3	Labels	AnI ER 13	LABLES			
G	Maintenance Manual					
G1	Product Life	#4.5	Life			
G2	Product Changes	AnII/V/VI 3.4				
H	Analysis of complaints/user feedback	AnII/V/VI 3.1	CCFB			
IJ	Location of responsibilities & /sub-contractors	AnII 3.1	Respon			
IJ1	Manufacturing route		MROUTE			
IJ2	Work Instructions and Tests		WINS			
IJ3	Sub Assemblies & Circuit Diagrams					
K	Literature Reviews		LITREV			
L	Packaging Trials and validation		PKTRIAL			
M	Quality Plan					
N	Sterilisation		STRMET			
O	MCA Licenses					
P	Design Files					
	Design Inputs					
	Design Documentation Checklist					
	Specification Brief		QC22			
	Time Scale		QC23			
	Job Progress		QC25			
	Compliance Essential req.					
	Preliminary drawings					
	Final Drawings					
	Working Drawings					
Section	Description	Ref MDD	Document		N/A	Done
	Design Changes					
	Validation					
R	Design Ouput	#4.4.4				
	Type examinations	AnV/VI				
	Test Reports/	AnII 3.2	TESTREP			
	Specification Tests					

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	EMC tests					
	Clinical Trial Reports	art 15 AnX	CTREP			
	Compatibility Trials					
	Biocompatibility	ANII 3.2c	BIOCOMP			
S	Final costings					
T	Photographs					
UV	Specifications of Materials		SPECMAT			
XYZ	Purchase specifications		PURCH			

