



Index of Technical Documentation

Section	Description	Ref MDD	Document	Status	N/A	Done
	Technical File					
	CD Amendment Controls		AMCOM	Not Done/ Needs More Infor/ Needs Tidying		
A	Reference to documents		DOCREP	Not Done/ Needs More Infor/ Needs Tidying		
B	EC Declaration of Conformance	AnII /V/VI	ECDEC	Not Done/ Needs More Infor/ Needs Tidying		
B1	Notified Body Certification			Not Done/ Needs More Infor/ Needs Tidying		
C	Essential Requirements	art 3	ERCHKP	Not Done/ Needs More Infor/ Needs Tidying		
C1	EN Standards	AnII 3.2c	ENstd	Not Done/ Needs More Infor/ Needs Tidying		
D	Classification Rationale Flow Chart	AnIX art II	Clasrat	Not Done/ Needs More Infor/ Needs Tidying		
D1	EMC Rationale		EMC	Not Done/ Needs More Infor/ Needs Tidying		
E	Risk Analysis	AnII 3.2c	RAISKAN	Not Done/ Needs More Infor/ Needs Tidying		
E1	Risk Analysis EN1441		RARCL	Not Done/ Needs More Infor/ Needs Tidying		
F	Description device w/drawing	AnII3.1	DDES	Not Done/ Needs More Infor/ Needs Tidying		
F1	Accessories	AnII 3.1	Access	Not Done/ Needs More Infor/ Needs Tidying		
F2	Instructions Microstim Microstim v2 Microstim DB Microstim DB v2	ER 13	INSTRUCT	Not Done/ Needs More Infor/ Needs Tidying		
F3	Labels	AnI ER 13	LABLES	Not Done/ Needs More Infor/ Needs Tidying		
G	Maintenance Manual Microstim V1 & V2 Microstim DB Microstim DB v2			Not Done/ Needs More Infor/ Needs Tidying		
G1	Product Life	#4.5	Life	Not Done/ Needs More Infor/ Needs Tidying		
G2	Product Changes	AnII/V/VI 3.4		Not Done/ Needs More Infor/ Needs Tidying		
HI	Analysis of complaints/user feedback	AnII/V/VI 3.1	CCFB	Not Done/ Needs More Infor/ Needs Tidying		
JK	Location of responsibilities & /sub-contractors	AnII 3.1	Respon	Not Done/ Needs More Infor/ Needs Tidying		
JK	Manufacturing route		MROUTE	Not Done/ Needs More Infor/ Needs Tidying		
JK	Work Instructions & Test Methods		WINS	Not Done/ Needs More Infor/ Needs Tidying		
JK	Sub Assembly and Circuit Diagrams Microstim V1 & V2 Microstim DB Microstim DB v2			Not Done/ Needs More Infor/ Needs Tidying		
L	Literature Reviews		LITREV	Not Done/ Needs More Infor/ Needs Tidying		
L	Packaging		PKTRIAL	Not Done/ Needs More Infor/ Needs Tidying		
M	Quality Plan			Not Done/ Needs More Infor/ Needs Tidying		
N	Sterilisation		STRMET	Not Done/ Needs More Infor/ Needs Tidying		
O	MCA Licenses			Not Done/ Needs More Infor/ Needs Tidying		
P	Design Files			Not Done/ Needs More Infor/ Needs Tidying		

	Microstim DB Microstim DBv2					
	Design Inputs			Not Done/ Needs More Infor/ Needs Tidying		
	Specification Brief		QC22	Not Done/ Needs More Infor/ Needs Tidying		
	Working Drawings			Not Done/ Needs More Infor/ Needs Tidying		
	Design Changes			Not Done/ Needs More Infor/ Needs Tidying		
	Validation			Not Done/ Needs More Infor/ Needs Tidying		
R	Design Ouput	#4.4.4		Not Done/ Needs More Infor/ Needs Tidying		
	Type examinations	AnV/VI		Not Done/ Needs More Infor/ Needs Tidying		
	Test Reports/	AnII 3.2	TESTREP	Not Done/ Needs More Infor/ Needs Tidying		
	Specification Tests			Not Done/ Needs More Infor/ Needs Tidying		
	EMC tests			Not Done/ Needs More Infor/ Needs Tidying		
	Clinical Trial Reports	art 15 AnX	CTREP	Not Done/ Needs More Infor/ Needs Tidying		
	Compatibility Trials			Not Done/ Needs More Infor/ Needs Tidying		
	Biocompatiblity	ANII 3.2c	BIOCOMP	Not Done/ Needs More Infor/ Needs Tidying		
S	Final costings			Not Done/ Needs More Infor/ Needs Tidying		
T	Photographs			Not Done/ Needs More Infor/ Needs Tidying		
UV	Specifications of Materials		SPECMAT	Not Done/ Needs More Infor/ Needs Tidying		
XYZ	Purchase specifications		PURCH	Not Done/ Needs More Infor/ Needs Tidying		