



Index of Technical Documentation

Section	Description	Ref MDD	Document	Status	N/A	Done
	Technical File					
	Amendment Controls (CD)		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	RG2	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	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	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			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		
H	Analysis of complaints/user feedback	AnII/V/VI 3.1	CCFB	Not Done/ Needs More Infor/ Needs Tidying		
IJ	Location of responsibilities & /sub-contractors	AnII 3.1	Respon	Not Done/ Needs More Infor/ Needs Tidying		
IJ1	Manufacturing route		MROUTE	Not Done/ Needs More Infor/ Needs Tidying		
K	Type examinations	AnV/VI		Not Done/ Needs More Infor/ Needs Tidying		
L	Test Reports/	AnII 3.2	TESTREP	Not Done/ Needs More Infor/ Needs Tidying		
				Not Done/ Needs More Infor/ Needs Tidying		
M	Clinical Trial Reports	art 15 AnX	CTREP	Not Done/ Needs More Infor/ Needs Tidying		
M1	Compatibility Trials			Not Done/ Needs More Infor/ Needs Tidying		
NO						
PQ	Literature Reviews		LITREV	Not Done/ Needs More Infor/ Needs Tidying		
R	Quality Plan			Viamed Procedures		
S	Design calculations	#4.4.4	DESCAL	Not Done/ Needs More Infor/ Needs Tidying		
T	Packaging Trials and validation		PKTRIAL	Not Done/ Needs More Infor/ Needs Tidying		
UV	Specifications of Materials		SPECMAT	Not Done/ Needs More Infor/ Needs Tidying		

UV1	Purchase specifications		PURCH	Not Done/ Needs More Infor/ Needs Tidying		
UV2	Work Instructions and Tests		WINS	Not Done/ Needs More Infor/ Needs Tidying		
W	Biocompatiblity	ANII 3.2c	BIOCOMP	Not Done/ Needs More Infor/ Needs Tidying		
XYZ	Sterilisation		STRMET	Not Done/ Needs More Infor/ Needs Tidying		