Index of Documentation.

Section.	Description.	Ref MDD / Ref ISO 9001.	Document.	Status.	A/NA.	Done.
i	Preliminary Outline		Introduction CD - Amendment control		A A	√ √
A	Index of documentation. Location of documents		Index of documentation. Location of documents.		A A	√ √
B	EC Declaration of conformance	Ann II, V, VI	Certificate(s)		A	√
	Notified body certification		Certificate(s)		A	√
	Certification BS EN ISO 9001:2000		Certificate(s)		A	√
	Certification ISO 13485:2003		Certificate(s)		A	√
	Certification - Patent		Trade Mark Certificate		A	√
C	Essential requirements	Art 3	Essential requirements		A	√
	EN standards	Ann II para 3.2c	EN Standards		A	√
D	Classification rationale Flow chart	Ann IX	Classification rationale Device Classification rules		A A	√ √
	EMC rationale		EMC rationale		A	√
	EMC report		EMC report		N/A	--
	Safety Classification Rationale		Rationale & BSI Classification		A	√
E	Risk analysis Class IIa Microstim	Ann II para 3.2c	Certificate(s)		A	√
	Reports		Risk Management Definitions Risk Analysis Report		A A	√ √
	EN ISO 14971:2001 Annex A		EN ISO 14971:2001 Annex A		A	√
	EN ISO 14971:2001 Annex D		EN ISO 14971:2001 Annex D		A	√
F	Description device	Ann II para 3.1	Description of Device		A	√
			Viamed Microstim leaflets		A	√
	Accessories	Ann II para 3.1	Description of accessories		A	√
	Instructions	Ann I para 13	User manual		A	√
	Labels	Ann I para 13	Labels		A	√
	Information		Training Document		N/A	--
G	Maintenance		Service Manual Service Procedures		N/A A	-- √
	Product life	Para 4.5	Product life		A	√
	Product changes	Ann II,V,VI para 3.4	Product changes		A	√
HI	Analysis of complaints/user feedback	Ann II, V, VI para 3.1 Art 15, Annexe X	Customer complaints, user feedback & Clinical Trials Product Reviews Medical Device Alerts		A A N/A N/A	√ √ -- --
JK	Location of responsibilities	Ann II para 3.1	Location of responsibilities		A	√
	Manufacturing route		Manufacturing route		A	√
	Work instructions and tests	VM3COP 36.01	W.I. & Test Method Tooling List Operating Instructions		A N/A A	√ -- √
	Sub assemblies & circuit diagrams		Electro-Technical Drawings		A	√
L	Literature reviews		RDG Fisher-Paykel Anaesthesia Asscoiates Bard Bio-medical Others as shown in file		A A A A A	√ √ √ √ √
M	Packaging trials and validation		Packaging Info Pictorial Info		A A	√ √
N	Quality Assurance	VM3COP 36.01 VM3COP36.02	Quality plan // // Test Instructions QA Agreements		A A N/A A	√ √ -- √

O	Sterilisation		Sterilisation		N/A	√
PQ	Not Used		---------		--	--
R	Components Breakdown		Complete Parts List		A	√
S	Photographs		Complete Unit & Accessories		A	√
T	Specifications of Materials		Approach Database		A	√
UV	Purchase specifications		Copy Purchase Orders		A	√
WX	Archives		List of Archived Documents		A	√
YZ	Design File		Contents Design Documentation		A A	√ √

Section.	Description.	Ref MDD / Ref ISO 9001.	Document.	Status.	A/NA.	Done.
YZ	Design File		Section Y – Design Input Section Z – Design Output		A A	
Y (01)	History & Theory		Introduction – Device History & Theory Design history		 A A	 √ √
Y (02)	Specification		Device Specification, QC22 Specification Brief		A N/A	√ --
Y (03)	Confidentiality Agreements		By Company Name		N/A	--
Y (04)	Design Calculations		Calculations Statement		A	√
Y (05)	Time Scale		Statement		A	√
Y (06)	Design Compliance		Compliance Statement		A	√
Y (07)	Project Progress		Project Diary Design and Development Statement		N/A N/A A	-- -- √
Y (08)	Work logs		Statement		A	√
Y (09)	Expenditure		Statement		A	√
Y (10)	Preliminary drawings		Sketches Drawings		N/A A	-- √
Y (11)	Final Drawings		Final drawing input		A	√
	Working Drawings		Final Viamed Drawings		A	√
Y (12)	Design Changes		QC 28 Copy Change Details		A A	√ √
Y (13)	Source codes		Source codes		A	√
Z (14)	Validation		Project Validation QC30		A	√
Z (15)	Design reviews		Statement		A	√
Z (16)	Purchases		Statement		A	√
Z (17)	Test reports	Ann II para 3.2	Statement		A	√
Z (18)	Final inspection & test		Statement		A	√
Z (19)	Type examinations	Ann V, VI	Statement		A	√
Z (20)	EMC tests & results		Statement		A	√
Z (21)	Bio-compatibility	Ann II para 3.2c	Statement		A	√
Z (22)	Compatibility Trials		Statement		A	√
Z (23)	Documentation		Checklist QC29		A	√