ARCHIVE DOCUMENTS

Section:	Description:	Document:	Archived
i	Preliminary Outline	Introduction Amendment control	√ √
A	Index of documentation. Location of documents	Index of documentation. Location of documents.	√ √
B	EC Declaration of conformance	Certificate(s)	√
	Notified body certification	Certificate(s)	√
	Certification BS EN ISO 9001:2000	Certificate(s)	√
C	Essential requirements	Essential requirements	√
	EN standards	EN Standards	√
D	Classification rationale Flow chart	Classification rationale Device Classification rules	√ √
	EMC rationale	EMC rationale	√
	EMC report	EMC report	N/A
E	Risk analysis Class IIb Tom Thumb	Certificate(s)	√
	Reports	Risk Management Definitions Risk Analysis Report	√ √
	EN ISO 14971:2001 Annex A	EN ISO 14971:2001 Annex A	√
	EN ISO 14971:2001 Annex D	EN ISO 14971:2001 Annex D	√
F	Description device	Description of Device	√
		Viamed Microstim leaflet	√
	Accessories	Description of accessories	√
	Instructions	User manual	√
	Labels	Labels	√
	Information	Training Document	N/A
G	Maintenance	Service Manual Service Procedures –	-- --
	Product life	Product life	√
	Product changes	Product changes	√
HI	Analysis of complaints/user feedback	Customer complaints User Feedback Product Reviews Medical Device Alerts	√ √ -- --
JK	Location of responsibilities	Location of responsibilities	√
	Manufacturing route	Manufacturing route	√
	Work instructions and tests	W.I. & Test Method Tooling List	√ --
	Sub assemblies & circuit diagrams	Electro-Technical Drawings	√
L	Literature reviews	H.P.C.S	√
M	Packaging trials and validation	Packaging Info Pictorial Info	√ --
N	Quality Plan	Quality plan QA Procedures Test Instructions QA Agreements	-- -- -- --
	Sterilisation	Sterilisation	√
O	Not Used	---------	--
PQ	Not Used	---------	--
R	Components Breakdown	Complete Parts List	--
S	Photographs	Original Microstim & accessories	--
T	Specifications of Materials	Accessories Components	√ √
UV	Purchase specifications	All Suppliers	√
WX	Archives	List of Archived Documents	--

Section.	Description.	Document.	Archived
O(01)	Device History & Theory	Device History & Theory Design history	
O(02)	Specification Brief	P03 – Specification Brief Device Specification, QC22	
O(03)	Confidentiality Agreements		
O(04)	Not Used		
O(05)	Time Scale	QC25	
O(06)			
O(07)	Project Progress	Project Diary QC25	
O(08)	Work logs		
O(09)	Expenditure		
O(10)	Not Used		
O(11)	Clinical evaluation	Clinical evaluation	
O(12)	Preliminary drawings		
O(13)	Risk assessment		
O(14)	Final Drawings		
	Working Drawings		
O(16)	Design Changes		
O(17)	Validation	Project Validation	
O(18)	Quotations		
O(19)	Source codes		
O(20)	Design reviews		
O(21)	Purchases		
O(22)	Test reports		
O(23)			
O(24)	Final inspection & test		
O(25)	Type examinations	IEC 601	
O(26)	EMC tests & results		
O(27)	Clinical Trial Reports		
O(28)	Biocompatiblity		
O(28)	Compatibility Trials		
O(30)	Final costings		
O(31)	Not Used		