

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	Classification rationale	√
	Flow chart	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	--
YZ	Design File	Semi complete file	√