

Index of Archive Documentation.

Section.	Description.	Document.	Archived.
i	Preliminary Outline	Introduction Amendment control	Yes Yes
A	Index of documentation. Location of documents	Index of documentation. Location of documents.	Yes Yes
B	EC Declaration of conformance	Certificate(s) x 2	Yes
	Notified body certification	Certificate(s)	N/A
	Certification BS EN ISO 9001:2000	Certificate(s)	N/A
	Certification ISO 13485:2003	Certificate(s)	N/A
C	Essential requirements	Essential requirements	Yes
	EN standards	EN Standards	Yes
D	Classification rationale & Decision Path	Classification rationale Device Classification rules Flow chart	Yes Yes Yes
	EMC rationale	EMC rationale	Yes
	EMC report	EMC report	No
E	Risk analysis Class IIb	Certificate	Yes
	Reports	Risk Management Definitions Risk Analysis Report	N/A No
	EN ISO 14971:2001 Annex A	EN ISO 14971:2001 Annex A	N/A
	EN ISO 14971:2001 Annex D	EN ISO 14971:2001 Annex D	N/A
F	Description device	Description of Device	Yes
		Viamed sPo2 Probe leaflets	Yes
	Accessories	Description of accessories	Yes
		Suppliers Leaflets	Yes
	Instructions	User manual	Yes
	Labels	Labels	Yes
G	Maintenance	Service Manual Service Procedures	N/A N/A
	Product life	Product life	Yes
	Product changes	Product changes	Yes
HI	Analysis of complaints/user feedback	Customer complaints, user feedback & Clinical Trials Product Reviews Medical Device Alerts	Yes
JK	Location of responsibilities	Location of responsibilities	Yes
	Manufacturing route	Manufacturing route	Yes
	Work instructions and tests	W.I. & Test Method Tooling List	Yes N/A
	Sub assemblies & circuit diagrams	Electro-Technical Drawings	Yes
L	Literature reviews	Various Reviews & Papers	No
M	Packaging trials and validation	Packaging Info	Yes
N	Quality Assurance	Quality plan QA Agreements	Yes No
O	Sterilisation	Sterilisation	Yes
PQ	Not Used	-----	--
R	Components Breakdown	Complete Parts List	Yes
S	Photographs	Originals & Accessories	Yes
T	Specifications of Materials	Components & Accessories	Yes / No
UV	Purchase specifications	Copy Purchase Orders	Yes
WX	Archives	List of Archived Documents	N/A
YZ	Design File	Contents Design Documentation	Yes