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i	Preliminary Outline		Introduction 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	√
	Representatives		Authority Statements		A	√
	FDA Approval		510K Statement		A	√
C	Essential requirements	Art 3	Essential requirements		A	√
	EN standards	Ann II para 3.2c	EN Standards		A	√
D	Classification rationale & Decision Path	Ann IX	Classification rationale Device Classification rules MHRA Rules – Diagram MDA Guidance Statement		A A A A	√ √ √ √
	EMC Status		EMC rationale EMC report		A A	√ √
E	Risk analysis Class IIb	Ann II para 3.2c	Certificates		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 of Device	Ann II para 3.1	Description of Device		A	√
			Viamed sPo2 Probe leaflets		A	√
			Cross Reference Charts		A	√
	Accessories	Ann II para 3.1	Description of accessories		A	√
			Suppliers Leaflets		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 Statement Service Procedures Sample		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 A A	√ √ √ √
JK	Location of responsibilities	Ann II para 3.1	Location of responsibilities		A	√
	Manufacturing route		Manufacturing route		A	√
	Work instructions and tests		W.I. & Test Method Tooling List Sample Procedure		A A A	√ √ √
	Supplier Information		Major Supplier Details		A	
	Sub assemblies & circuit diagrams		Electro-Technical Drawings		A	√
L	Literature reviews		Various Reviews & Papers		A	√
M	Packaging trials and validation		Packaging Info Pictorial Info		A A	√ √
N	Quality Assurance		Quality plan Supplier Certificates QA Agreements		A A A	√ √ √

O	Sterilisation		Sterilisation Statement		A	√
PQ	Not Used		---------		N/A	--
R	Components Breakdown		Complete Parts List		A	√
S	Photographs		Complete Units & Accessories		A	√
T	Specifications of Materials		Statement – Volume 3		A	√
UV	Purchase specifications		Copy Purchase Orders		A	√
WX	Documentation		Design Checklist QC29		A	√

Y (01)	History & Theory		Design History Device Theory SpO2 Principles		A A A	√ √ √
Y (02)	Specification		Specification Brief _QC22		A	√
Y (03)	Confidentiality Agreements		Agreements		N/A	--
Y (04)	Design Calculations		Calculations Statement		A	√
Y (05)	Time Scale		UDT Timescales Viamed Timescales QC23		A A	√ √
Y (06)	Design Compliance		Compliance Statement		A	√
Y (07)	Project Progress		Project Diary Design Progress QC 25 Tooling Progress Teledyne Progress		A A A A	√ √ √ √
Y (08)	Work logs		Statement		A	√
Y (09)	Expenditure		Various Quotations		A	√
Y (10)	Preliminary drawings		Sketches Drawings – Volume Four		A A	√ √
Y (11)	Final Drawings		Final Supplier Drawings- Vol4		A	√
	Working Drawings		Final Viamed Drawings- Vol4		A	√
Y (12)	Design Changes		Design Changes QC 28 Copy Change Details		A A	√ √
Y (13)	Source codes		Statement		N/A	--
Z (14)	Validation		Project Validation QC30		A	√
Z (15)	Design reviews		Reviews_QC24		A	√
Z (16)	Purchases		Final Costings		A	√
Z (17)	Test reports	Ann II para 3.2	Reports & Results Spectral Analysis Results		A A	√ √
Z (18)	Final inspection & test		UDT Final Inspections Viamed QA Procedures		A	√
Z (19)	Type examinations	IEC 601	Test Results		A	√
Z (20)	EMC tests & results		Laboratory Results		A	√
Z (21)	Bio-compatibility	Ann II para 3.2c	Statement		A	√
Z (22)	Compatibility Trials		Trials Report Background Factors Compatibility Tables		A A A	√ √ √

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Section.	Description.	Document.	Archived.
i	Preliminary Outline	Introduction Amendment control	Yes Yes
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B	EC Declaration of conformance	Certificate(s) x 2	Yes
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	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 Defnitions 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

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YZ	Design File	Contents Design Documentation	Yes