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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 Reports	Ann II para 3.2c	Certificates Risk Management Definitions Risk Analysis Report		A A A	√ √ √
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	EN ISO 14971:2001 Annex D		EN ISO 14971:2001 Annex D		A	√
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	Accessories	Ann II para 3.1	Description of accessories Suppliers Leaflets		A A	√ √
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	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	√ √ √ √
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	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 Working Drawings		Final Supplier Drawings- Vol4 Final Viamed Drawings- Vol4		A A	√ √
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Y (13)	Source codes		Statement		N/A	--
Z (14)	Validation		Project Validation QC30		A	√
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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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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

T:\Kevin Rush\CE Files\CE files current\SpO2 Probes\SpO2 Probes_CE File_2004\WX.
Archives\WX. Archive Documentation_SpO2 Probes.doc
30/04/04

Index of Technical Documentation

Description	Section	Ref MDD	Document	Status	N/A	Done
Technical File	Book 1					
CD Amendment Controls			AMCOM	Not Done/ Needs More Infor/ Needs Tidying		
Index of Technical Documetation						
Location of documents	A		DOCREF	Not Done/ Needs More Infor/ Needs Tidying		
EC Declaration of Conformance	B	AnII /V/VI	ECDEC	Not Done/ Needs More Infor/ Needs Tidying		
Notified Body Certification	B1			Not Done/ Needs More Infor/ Needs Tidying		
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EN Standards	C1	AnII 3.2c	ENstd	Not Done/ Needs More Infor/ Needs Tidying		
Classification Rationale MDA correspondence I Ib BCI Oxilink	D	AnIX art II	Clasrat	Not Done/ Needs More Infor/ Needs Tidying		
EMC Rationale	D1		EMC	Not Done/ Needs More Infor/ Needs Tidying		
Risk Analysis Dolphin	E	AnII 3.2c	RAISKAN	Not Done/ Needs More Infor/ Needs Tidying		
Risk Analysis EN1441	E1		RARCL	Not Done/ Needs More Infor/ Needs Tidying		
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Literature Reviews	K		LITREV	Not Done/ Needs More Infor/ Needs Tidying		
Packaging Trials and validation	L		PKTRIAL	Not Done/ Needs More Infor/ Needs Tidying		
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QA Bayer QA BC QA Cablemaster Opto Sensors	M1					

510K BCI	M2					
QA Procedures						
Sterilisation	NO		STRMET	Not Done/ Needs More Infor/ Needs Tidying		
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Specification Brief	P3		QC22	Not Done/ Needs More Infor/ Needs Tidying		
Time Scale	P4		QC23	Not Done/ Needs More Infor/ Needs Tidying		
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Compliance Essential req.				Not Done/ Needs More Infor/ Needs Tidying		
Preliminary drawings				Not Done/ Needs More Infor/ Needs Tidying		
Final Drawings				Not Done/ Needs More Infor/ Needs Tidying		
Working Drawings				Not Done/ Needs More Infor/ Needs Tidying		
Design Changes				Not Done/ Needs More Infor/ Needs Tidying		
Validation				Not Done/ Needs More Infor/ Needs Tidying		
Design review						
Description	Section	Ref MDD	Document	Status	N/A	Done
Design Output	R	#4.4.4		Not Done/ Needs More Infor/ Needs Tidying		Y
Test Reports/ MCI Finger probe test data	R1	AnII 3.2	TESTREP	Not Done/ Needs More Infor/ Needs Tidying		
Final Inspection & Test UDT						
Type examinations IEC601		AnV/VI		Not Done/ Needs More Infor/ Needs Tidying		
EMC tests	R2			Not Done/ Needs More Infor/ Needs Tidying		
Clinical Trial Reports	R3	art 15 AnX	CTREP	Not Done/ Needs More Infor/ Needs Tidying		
Biocompatibility	R10	ANII 3.2c	BIOCOMP	Not Done/ Needs More Infor/ Needs Tidying		
Compatibility Trials Factors effecting accuracy Compatibility Charts Nellcor Spacelabs Cross reference MCI Probe Range 97 MCI Probe range 98	R4			Not Done/ Needs More Infor/ Needs Tidying		
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Prototypes	R8					
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Final costings	S			Not Done/ Needs More Infor/ Needs Tidying		
Photographs	T			Not Done/ Needs More Infor/ Needs Tidying		



VIAMED

OEM Photographs Nelcor Ohmeda						
Specifications of Materials	UV		SPECMAT	Not Done/ Needs More Infor/ Needs Tidying		
Springs	Bk 3					
Strain relief						
Buttons						
Support Frames						
Cable	Bk4					
DB9 covers						
DB9 cable assy						
Shells	BK5					
Hard Pads						
Soft Pads						
LED's	Bk6					
LED misc						
LED suppliers						
Lincoln Tests						
Connectors	Bk7					
Purchase specifications	XYZ		PURCH	Not Done/ Needs More Infor/ Needs Tidying		
Parts List	Z1					
Production Picking Lists						
Components						
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Description	Ref MDD	Viamed Document	Status	N/A	Done
Technical File					
Index of Technical Documentation			Not Done/ Needs More Infor/ Needs Tidying		
Location of documents			Not Done/ Needs More Infor/ Needs Tidying		
EC Declaration of Conformance	AnII /V/VI		Not Done/ Needs More Infor/ Needs Tidying		
Notified Body Certification			Not Done/ Needs More Infor/ Needs Tidying		
Authorised representative			Not Done/ Needs More Infor/ Needs Tidying		
Essential Requirements MDD	art 3		Not Done/ Needs More Infor/ Needs Tidying		
EN Standards	AnII 3.2c		Not Done/ Needs More Infor/ Needs Tidying		
Classification Rationale	AnIX art II		Not Done/ Needs More Infor/ Needs Tidying		
EMC Rationale			Not Done/ Needs More Infor/ Needs Tidying		
Risk Analysis Dolphin Aristo Viamed	AnII 3.2c		Not Done/ Needs More Infor/ Needs Tidying		
Risk Analysis EN1441 Dolphin Aristo Viamed			Not Done/ Needs More Infor/ Needs Tidying		
Description device w/drawing Leaflet Photographs of common types Schematic diagrams of probes	AnII3.1		Not Done/ Needs More Infor/ Needs Tidying		
Accessories	AnII 3.1		Not Done/ Needs More Infor / Needs Tidying		
Instructions Translations	ER 13		Not Done/ Needs More Infor/ Needs Tidying		
Labels	AnI ER 13		Not Done/ Needs More Infor/ Needs Tidying		
Maintenance Manual			Not Done/ Needs More Infor/ Needs Tidying		
Manufacturing procedures					
Product Life	#4.5		Not Done/ Needs More Infor/ Needs Tidying		
Product Changes	AnII/V/VI 3.4		Not Done/ Needs More Infor/ Needs Tidying		
Analysis of complaints/user feedback	AnII/V/VI 3.1		Not Done/ Needs More Infor / Needs Tidying		
Location of responsibilities & /sub-contractors	AnII 3.1		Not Done/ Needs More Infor/ Needs Tidying		
Manufacturing route			Not Done/ Needs More Infor / Needs Tidying		
Work Instructions and Tests			Not Done/ Needs More Infor/ Needs Tidying		
Literature Reviews			Not Done/ Needs More Infor/ Needs Tidying		
Packaging Trials and validation					



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Packaging Trials and validation	L		PKTRIAL	Not Done/ Needs More Infor/ Needs Tidying		

Quality Plan MCI UDT PDI	M			Not Done/ Needs More Infor/ Needs Tidying		
QA Bayer QA BC QA Cablemaster Opto Sensors	M1					
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Comparisons	R6					
OEM's	R7					

Prototypes	R8					
Viamed	R9					
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Strain relief						
Buttons						
Support Frames						
Cable	Bk4					
DB9 covers						
DB9 cable assv						
Shells	BK5					
Hard Pads						
Soft Pads						
LED's	Bk6					
LED misc						
LED suppliers						
Lincoln Tests						
Connectors	Bk7					
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