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i	Preliminary Outline	Introduction	Yes
NE.		Amendment control	Yes
Α	Index of documentation.	Index of documentation.	Yes
	Location of documents	Location of documents.	Yes
	EC Declaration of conformance	Certificate(s) x 2	Yes
В	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
	Essential requirements	Essential requirements	Yes
	EN standards	EN Standards	Yes
	Classification rationale &	Classification rationale	Yes
	Decision Path	Device Classification rules	Yes
D	Decision Fath	Flow chart	Yes
	EMC rationale	EMC rationale	Yes
	EMC report	EMC report	No
	Risk analysis Class IIb	Certificate	Yes
	•	Risk Management Defnitions	N/A
E	Reports	Risk Analysis Report	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
	Description device	Description of Device	Yes
	25551,541513 454165	Viamed sPo2 Probe leaflets	Yes
	Accessories	Description of accessories	Yes
F	Accessories	Suppliers Leaflets	Yes
	Instructions	User manual	Yes
	Labels	Labels	Yes
	Labels	Service Manual	N/A
	Maintenance		N/A N/A
G	Product life	Service Procedures Product life	Yes
	Product changes	Product changes	Yes
		Customer complaints, user feedback &	
HI	Analysis of complaints/user feedback	Clinical Trials	Yes
		Product Reviews	
	1 99	Medical Device Alerts	
	Location of responsibilities	Location of responsibilities	Yes
IIZ.	Manufacturing route	Manufacturing route	Yes
JK	Work instructions and tests	W.I. & Test Method	Yes
	The gard appropriate the analysis of the second and the second and the second appropriate the second appropriate the second and the second an	Tooling List	N/A
	Sub assemblies & circuit diagrams	Electro-Technical Drawings	Yes
L	Literature reviews	Various Reviews & Papers	No
М	Packaging trials and validation	Packaging Info	Yes
Ν	Quality Assurance	Quality plan QA Agreements	Yes No
0	Sterilisation	Sterilisation	Yes
PQ	Not Used	oternisation ,	
R	Components Breakdown	Complete Parts List	
S	Photographs		
T	Specifications of Materials	Components & Accessories	Yes Yes / No
UV	Purchase specifications	Components & Accessories Copy Purchase Orders	Yes
WX		List of Archived Documents	N/A
VVV	Archives	Contents	I IV/A
YZ	Design File	LACHIERUS	Yes

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	Instructions	User manual	Yes	
	Labels	Labels	Yes	
		Service Manual	N/A	
	Maintenance	Service Procedures	N/A	
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	Analysis of complaints/user feedback	Clinical Trials		
HI		Product Reviews	Yes	
		Medical Device Alerts		
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		Contents		
YZ	Design File	Design Documentation	Yes	