

Index of Documentation.

Section.	Description.	Ref MDD / Ref ISO 9001.	Document.	Status.	A/NA.	Done.
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	√
	Product Trade Mark		Certificate		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 Device Classification rules		A A A	√ √ √
	EMC rationale		EMC rationale		N/A	√
	EMC report		EMC report		N/A	--
E	Risk analysis Class IIb Tom Thumb	Ann II para 3.2c	Certificate(s)		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 device	Ann II para 3.1	Description of Device		A	√
			Viamed Tom Thumb leaflet		A	√
	Accessories	Ann II para 3.1	Description of accessories		A	√
	Instructions	Ann I para 13	User manual		A	√
	Labels	Ann I para 13	Labels		A	√
	Information		Training Document		A	√
G	Maintenance		Service Manual Service Manual - Valves Service Procedures		A 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		A	√
			Product Reviews		A	√
			Medical Device Alerts		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		A A	√ √
	Sub assemblies & circuit diagrams		Electro-Technical Drawings		N/A	--
L	Literature reviews		Fisher & Paykel Neo-puff		A	√
M	Packaging trials and validation		Packaging Info		A	√
			Pictorial Info		A	√
N	Quality Plan		Quality plan		A	√
			Test Instructions		A	√
			QA Agreements		N/A	√
O	Sterilisation		Sterilisation		A	√
PQ	Not Used		-----		N/A	--

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R	Components Breakdown		Complete Parts List		A	√
S	Photographs		Original Tom Thumb & accessories		A	√
T	Specifications of Materials		Accessories, Block, Clamping, Connectors, Flowmeters, Valves, Labels		A	√
UV	Purchase specifications		Therapy Equipment, G & R Hydroparts, Newsham Engineering, WIKA, MAJ		A	√
WX	Archives		List of Archived Documents		A	√
YZ	Design File		Contents Design Documentation		A A	√ √

Section.	Description.	Ref MDD / Ref ISO 9001.	Document.	Status.	A/NA.	Done.
YZ	Design File		Section Y – Design Input Section Z – Design Output		A A	√ √
Y(01)	History & Theory		Introduction – Device History & Theory Design history		A A	
Y(02)	Specification		Device Specification, QC22 Specification Brief		A A	√ √
Y(03)	Confidentiality Agreements		By Company Name		A	
Y(04)	Design Calculations		Calculations Flow Rates		A A	√ √
Y(05)	Time Scale		QC23		A	√
Y(06)	Design Compliance		Compliance Matrix		A	√
Y(07)	Project Progress		Project Diary Design and Development QC25 Progress Report		N/A A A	-- √ √
Y(08)	Work logs		QC 26		A	√
Y(09)	Expenditure		QC 27 Purchases		A	√
Y(10)	Preliminary drawings		Sketches Drawings		A A	√ √
Y(11)	Final Drawings Working Drawings		Final drawing input Final Viamed Drawings		A A	√ √
Y(12)	Design Changes		QC 28		A	√
Y(13)	Source codes		Source codes		N/A	--
Z(14)	Validation		Project Validation QC30		A	√
Z(15)	Design reviews		QC 24		A	√
Z(16)	Purchases		Copy Purchase Orders		A	√
Z(17)	Test reports	Ann II para 3.2	Various reports		A	√
Z(18)	Final inspection & test		Internal Test results		A	√
Z(19)	Type examinations	Ann V, VI	IEC 601		A	√
Z(20)	EMC tests & results		Statement		A	√
Z(21)	Bio-compatibility	Ann II para 3.2c	Statement		A	√
Z(22)	Compatibility Trials		Statement		A	√
Z(23)	Documentation		Checklist QC29		A	√

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