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	√
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 MHRA Rules – Diagram		A A A	√ √ √
	EMC Status		EMC rationale EMC report	Update	A N/A	√ --
E	Risk analysis Class I	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 Timer leaflet	Update	A	√
	Accessories	Ann II para 3.1	Description of accessories		A	√
	Instructions	Ann I para 13	User manual	Update	A	√
	Labels	Ann I para 13	Labels	Update	A	√
	Information		Training Document		N/A	--
G	Maintenance		Service Manual Statement		A	√
	Product life	Para 4.5	Product life		A	√
	Product changes	Ann II,V,VI - 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	Update	A	√
	Manufacturing route		Manufacturing route	Update	A	√
	Work instructions and tests		W.I. & Test Method	Update	A	√
	Supplier Information		Major Supplier Details	Update	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	Update	A A	√ √
N	Quality Assurance		Quality plan QA Agreements	Update	A A	√ √
O	Sterilisation		Sterilisation Statement		A	√
PQ	Not Used		---------		N/A	--
R	Components Breakdown		Complete Parts List	Update	A	√
S	Photographs		Complete Units & Accessories		A	√
T	Specifications of Materials		Copy Spec Sheets	Update	A	√
UV	Purchase specifications		Copy Purchase Orders	Update	A	√
WX	Archives		List of Archived Documents		A	√
YZ	Design File – Volume 2		Contents Design Documentation		A A	√ √

Section.	Description.	Ref MDD / Ref ISO 9001.	Document.	Status.	A/NA.	Done.
YZ	Design File – Volume 2		Section Y – Design Input Section Z – Design Output		A A	√ √
Y (01)	History & Theory		Design History Device Theory		A A	√ √
Y (02)	Specification		Specification Brief		A	√
Y (03)	Confidentiality Agreements		Agreements		N/A	--
Y (04)	Design Calculations		Calculations Statement		A	
Y (05)	Time Scale		Viamed Timescales		A	
Y (06)	Design Compliance		Compliance Statement		A	
Y (07)	Project Progress		Design Progress	Update	A	√
Y (08)	Work logs		Statement		A	
Y (09)	Expenditure		Various Quotations		A	
Y (10)	Preliminary drawings		Sketches Drawings		A A	
Y (11)	Final Drawings		Final Supplier Drawings		A	
	Working Drawings		Final Viamed Drawings	Update	A	√
Y (12)	Design Changes		Design Changes QC 28 Copy Change Details		A A	
Y (13)	Source codes		Statement		A	
Z (14)	Validation		Project Validation QC30		A	
Z (15)	Design reviews		Reviews / Minutes		A	
Z (16)	Purchases		Final Costings		A	
Z (17)	Test reports	Ann II para 3.2	Reports & Results		A	
Z (18)	Final inspection & test		Viamed QA Procedures		A	
Z (19)	Type examinations	IEC 601	Test Results		N/A	--
Z (20)	EMC tests & results		Laboratory Results		N/A	--
Z (21)	Bio-compatibility	Ann II para 3.2c	Statement		A	
Z (22)	Compatibility Trials		Trials Report Background Factors		A A	
Z (23)	Documentation		Checklist QC29		A	