A : Index of Technical Documentation.

Section.	Description.	MDD ref.	Document name.	Status.	A/NA.	Done.
(i)	CD amendment controls.		CD amendment controls.			
A	Index & location of documents.		Index of documentation.			
			Location of documents.			
B	Certificates.	Annex II, V & VI.	Declaration of conformity : APGAR timer.			
			Viamed Ltd : EC QA certification.			
			Viamed Ltd : Certificate of registration to BS EN ISO 9001 : 1994.			
			Notified body certification.			
			Authorised representative.			
C	Essential requirements & applicable standards.	Article 3.	Essential Requirements.			
		Annex II para 3.2c.	EN Standards.			
D	Device classification & flowchart.	Annex IX. Art II.	Classification rational.			
D	Flow Chart.		Rationale Flow Chart			
D1	EMC Rationale.		EMC Report.			
E	Risk management.	Annex II para 3.2c.	Risk analysis report.			
			Risk assessment, EN ISO 14971 Annex A.			
			Risk assessment, EN ISO 14971 Annex D.			
F	Device description.	Annex II para 3.1.	Device description, drawing, photos etc.			
		Annex II para 3.1.	Accessories.			
		Annex I para 13.	Instructions. Inserts.			
		Annex I para 13.	Labels.			
			Maintenance manual.			
G	Product lifespan.		Product Life.			
		Annex II para 3.4.	Product Changes.			
H	Analysis of complaints & feedback.	Annex II para 3.1.	Analysis of complaints / user feedback.			
IJ	Manufacturing plan.	Annex II para 3.1.	Location of responsibilities.			
			Manufacturing route.			
			Work instructions and tests.			
			Sub assemblies & circuit diagrams.			
K	Literature reviews.		Literature reviews.			
L	Packaging trials and validation.		Packaging trials and validation.			
M	Quality documentation.		Quality Plan.			
N	Sterilisation.		Sterilisation.			
O	MCA Licenses.		MCA Licenses.			
PQ	Design : Input.		Contents.			
			Design documentation checklist.			
			Specification brief.			

			Time scale.			
			Job progress.			
			Work logs.			
			Expenditure.			
			Compliance Essential req.			
			Preliminary drawings.			
			Preliminary drawings.			
			Final Drawings.			
			Working Drawings.			
			Design review.			
			Design changes.			
R	Design : Output.	Annex II para 3.2.	Test Reports.			
		Annex V & VI.	Type examinations IEC601.			
			EMC tests.			
			Specification Tests.			
		Art 15, Annex X.	Clinical Trial Reports.			
			Compatibility Trials.			
		Annex II para 3.2c.	Biocompatiblity.			
			Validation.			
S	Costings.		Final cost.			
T	Photographs.		Photographs.			
UV	Specifications of materials.		Specifications of materials.			
XYZ	Purchase specifications.		Purchase specifications.			