

VM3COP23.03 PAQ Documents Required

List of Variants	Price List if available, if not self generate from stock group
List of Accessories	Price List if available, if not self generate from stock group
GTIN Numbers	If PAQ for one variant, add to PAQ form. If for group of variants, generate GTIN list from stock group and add to technical files CH1.05
Device Brochure/Specification	Leaflet and/or Data/Specification Sheet
Manufacturer EC Declaration of Conformity	From Document Index
Manufacturer ISO 13485:2016 Certificate	From Document Index
Viamed ISO 13485:2016 Certificate	From Document Index
Warranty Details	Generated from stock page and uploaded to Technical Files G 6
End of Life Waste Management	General Disposal Document, Oxygen Sensor Disposal Service (if applicable), User Manual (if included), RoHS & REACH Declaration
Post Delivery Inspection	User Manual
Installation Requirements	User Manual
Service Contract Options	Viamed Labour Rates and Charges
Availability of Spare / Replacement Parts	Price List if available, if not self generate from stock group
Information/Equipment/Tooling/Software Requirements For servicing	User Manual
Decontamination Instructions Protocols	User Manual
Information Capture Encryption ...	User Manual
Device IT Software Hardware Requirements	User Manual
IT Cybersecurity	User Manual
Hazards that require special safety measurements	User Manual / Safety Data Sheet MSDS
Performance Quality Assurance Measures	User Manual
User Training Offered	Viamed Policy on End-User Training
Technical Training Offered	Viamed Policy on End-User Training
Decontamination Training Offered	NONE
Additional Support Facilities Offered	Viamed Policy on End-User Training