RiviaMed Compliance Partners

Development Process	Design Control Process	Step	Quality Record	Software as a Medical Device (SaMD)	Non-Active Devices/Accessories (Heart Valves, catheters)	Non-Active Implantable - Combo Product (Lead, TAVR)	Active Implantable + Firmware (IPG, ICD, UND)	Active Implantable - Combo Product + Firmware (MI VR)	Non-Medical Health Software (Non-MDS)	External Device + Firmware (EPG, Programmer)
Design Planning	Design & Development Planning	Plan the Design	Design Plan	✓	✓	✓	✓	✓	✓	✓
			DHF Index	✓	✓	✓	✓	✓	✓	✓
		Initiate the Design	Documented Design Review Report - Design Initiation	✓	✓	✓	✓	✓	✓	✓
	Design Input Requirements	Define the Design Input Requirements	Design Input Requirements	✓	✓	✓	✓	✓	✓	✓
			Traceability Matrix	✓	✓	✓	✓	✓		✓
	Risk Management	Plan Product Risk Management	Risk Management Plan	✓	✓	✓	✓	✓	✓	✓
		Assess Black Box Solution Risks	Safety Characteristics Analysis	✓	✓	✓	✓	✓	✓	✓
			Hazard Analysis Log	✓	✓	✓	✓	✓	✓	✓
Design Development	Risk Management	Assess Design Risks	Use Error Analysis	✓	✓	✓	✓	✓	✓	✓
			Product Design Failure Analysis	✓	✓	✓	✓	✓	✓	✓
			Hazard Analysis Log	✓	✓	✓	✓	✓	✓	✓
	Design	Create the Design	Design Output Specifications	✓	✓	✓	✓	✓	✓	✓
			Pharmaceutical Justification of Specification (JOS)			✓		✓		
			Traceability Matrix	✓	✓	✓	✓	✓	✓	✓
			Engineering Bill of Materials (EBOM)		✓	✓	✓	✓		✓
			Software/Firmware Source	✓			✓	✓	✓	✓
			Software/Firmware Build Record	✓			✓	✓	✓	✓
	Design Verification	Develop Verification Plan(s)	Design Verification Plan	✓	✓	✓	✓	✓	✓	✓
			Traceability Matrix	✓	✓	✓	✓	✓		✓
		Verify the Design	Design Verification Report	✓	✓	✓	✓	✓	✓	✓
Design Completion	Risk Management	Verify Risk Controls	Hazard Analysis Log	✓	✓	✓	✓	✓	✓	✓
		Evaluate Residual Risk Acceptability	Risk Management Report	✓	✓	✓	✓	✓	✓	✓
	Design Validation	Develop Validation Plan(s)	Design Validation Plan	✓	✓	✓	✓	✓	✓	✓
			Production Equivalent Unit Build Readiness		✓	✓	✓	✓		✓
			Traceability Matrix	✓	✓	✓	✓	✓		✓
		Validate the Design	Production State Equivalency		✓	✓	✓	✓		✓
			Design Validation Report	✓	✓	✓	✓	✓	✓	✓
		Assess Production State	Production State Equivalency		✓	✓	✓	✓		✓
			SOUP Item List	✓			✓	✓	✓	✓
			Software Anomaly Assessment	✓			✓	✓	✓	✓
			Notable Software Anomalies	✓			✓	✓	✓	✓
	Design Transfer	Prepare Software Release	Release Record	✓			✓	✓	✓	✓
			Software Bill of Materials (SBOM)	✓			✓	✓	✓	✓
		Assess the Design Transfer	Documented Design Review Report - Design Transfer		✓	✓	✓	✓		✓
	Design & Development Planning	Close the Design	Documented Design Review Report - Design Closure	✓	✓	✓	✓	✓	✓	✓
Change Design	Design Change	Plan the Change	Design Change Record	✓	✓	✓	✓	✓	✓	✓
		Initiate the Change	Documented Design Review Report - Change Initiation	✓	✓	✓	✓	✓		✓
		Complete the Change	Design Change Record	✓	✓	✓	✓	✓	✓	✓
			Documented Design Review Report - Change Closure	✓	✓	✓	✓	✓		✓
Multiple			Documented Design Review Report	✓	✓	✓	✓	✓		✓
			Issue Record	✓	✓	✓	✓	✓	✓	✓
			Documented Design Review Report - Issue Escalation	✓	✓	✓	✓	✓	✓	✓
			Method Validation Record	✓	✓	✓	✓	✓		✓

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