

Type	Risk Class	DocID	Version	Title	Owner role	Owner name
Process	Medium	QM		Quality Management		
SOP	Medium	M-QM	01	Quality Manual		
Annex		M-QI	this doc	Qms Index		
Annex		M-QD	01	Qms Dashboard		
Annex		M-QT	01	Qms Terms		
Annex		M-QR	01	QMS Roles		
Annex		M-QFC	01	QMS Flow Charts		
SOP	Medium	P-DR	01	Document and Record control		
Template		T-QP	see SOP	Qms Procedure		
Template		T-QW	see SOP	Qms Work instruction		
Template		T-QRW	see SOP	Qms Record ms Word		
Template		T-QRE	see SOP	Qms Record ms Excel		
Template		T-MEM	see SOP	MEMo		
Template		T-LS	see SOP	Log Sheet		
Template		T-PP	see SOP	master Power Point		
Template		T-DRC	see SOP	Document Review Checklist		
Template		T-MOM	see SOP	Minutes Of Meeting		
SOP	Medium	P-CA	01	CAPA		
Template		T-CA	01	CAPA form		
SOP	Low	P-AD	01	Analysis of Data		
SOP	Medium	P-AU	01	Internal and Supplier audits		
Template		T-IAR	see SOP	Internal Audit Report		
Template		T-SAR	see SOP	Supplier Audit Report		
SOP	Medium	P-MR	01	Management Review		
Template		T-MRR	see SOP	Management Review Report		
Process	Medium	DC		Design Control		
SOP	Low	P-DLC	01	Design Life Cycle		
Template		T-DHFW	see SOP	master DHF document Ms-word		
Template		T-DHFF	see SOP	master DHF form Ms-word		
Template		T-DHFE	see SOP	master DHF document Ms-excel		
Template		T-DMRW	see SOP	master DMR document Ms-word		
Template		T-CRS	see SOP	Commercial Requirements Spec		
Template		T-DD	see SOP	Device Description		
Template		T-SRS	see SOP	System Requirements Spec		
Template		T-SSRS	see SOP	Subsystem Requirements Spec		
Template		T-LRS	see SOP	Labeling Requirements Spec		
Template		T-RTM	see SOP	Requirements Traceability Matrix		
Template		T-SAS	see SOP	System Architecture Spec		
Template		T-ESS	see SOP	Electrical Safety Strategy Specification		
Template		T-DFMEA	see SOP	Design FMEA		
Template		T-VS	see SOP	Verification Spec		
Template		T-VR	see SOP	Verification Report		
Template		T-VVP	see SOP	Verification and Validation Plan		
Template		T-VVR	see SOP	Verification and Validation Report		
Template		T-SRN	see SOP	System Release Notes		
Template		T-PMP	see SOP	Project Management Plan		
Template		T-RSP	see SOP	Regulatory Strategy Plan		
Template		T-DRR	see SOP	Design Review Report		
Template		T-PER	see SOP	Project Evaluation Report		
Template		T-MR	see SOP	Milestone Report		
Template		T-DTAR	see SOP	Design Transfer Acceptance Report		
SOP	Medium	P-RM	01	Risk Management		
Template		T-RMP	see SOP	Risk Management Plan		
Template		T-RMM	see SOP	Risk Management Matrix		
Template		T-RMR	see SOP	Risk Management Report		
Template		T-RMER	see SOP	Risk Management Evaluation Report IEC 60601-1		
SOP	Medium	P-UE	01	Usability Engineering		
Template		T-UEP	see SOP	Usability Engineering Plan		
Template		T-UIS	see SOP	User Interface Spec		
Template		T-SER	see SOP	Summative Evaluation Report		
Template		T-UER	see SOP	Usability Engineering Report		
Template		T-USS	see SOP	Use Scenario Specification		
Template		T-UIEP	see SOP	User Interface Evaluation Plan		
Template		T-FER	see SOP	Formative Evaluation Report		
SOP	Medium	P-SWD	01	Software Development		
Template		T-SWAS	see SOP	Software Architectures Spec		
Template		T-SRER	see SOP	Software Risk Evaluation Report		
Template		T-SWCTR	see SOP	Software Change Test Report		
Template		T-SWCMR	see SOP	Software Configuration Management Report		
Template		T-SRN	see SOP	System Release Note		
Guideline		T-SWCS	01	Software Coding Standard		
Work instruction		W-SCM	01	Software Configuration Management		

Template		T-82CR	see SOP	IEC82304-1 Compliance Report		
Template		T-62R	see SOP	IEC62304 Compliance Report		
SOP	Medium	P-DCM	01	Design Change Management		
Template		T-CRPR	see SOP	CR PR form		
SOP	Medium	P-CE	01	Clinical Evaluation including PMCF		
Template		T-PSPR	see SOP	Preclinical Study Plan / Report		
Template		T-CEP	see SOP	Clinical Evaluation Plan		
Template		T-CER	see SOP	Clinical Evaluation Report		
Template		T-CCR	see SOP	Clinical Complications Report		
SOP	Medium	P-CI	01	Clinical Investigation		
Template		T-CIP	see SOP	Clinical Investigation Plan		
Template		T-CIR	see SOP	Clinical Investigation Report		
Template		T-CRF	see SOP	Case Report Form (CRF)		
Template		T-ISS	see SOP	Investigation Site Selection report (ISS)		
Template		T-AER	see SOP	Adverse Event Report form		
Template		T-IMDD	see SOP	Investigational Medical Device Dossier (IMDD)		
Template		T-IB	see SOP	Investigator Brochure (IB)		
Template		T-CMR	see SOP	Clinical Monitoring report		
Template		T-CTA	see SOP	Clinical Trial Agreement (CTA)		
Template		T-ICF	see SOP	Informed Consent Form		
Process	High	PR		Production		
SOP	High	P-PR	01	Production and Release		
Template		T-PSS	see SOP	Product Specification Sheet		
Template		T-PPF	see SOP	Production Process Flow		
Template		T-MSS	see SOP	Material Specification Sheet		
Template		T-PFMEA	see SOP	Process FMEA		
Template		T-IISR	see SOP	Incoming Inspection Sheet (IIS) or Report (IIR)		
Template		T-PISR	see SOP	Production Instruction Sheet (PIS) or Report (PIR)		
Template		T-FISR	see SOP	Final Instruction Sheet (FIS) or Report (FIR)		
SOP	Medium	P-NC	01	Control of Nonconforming product		
Template		T-NCR	see SOP	Non-Conformity Report		
Process	High	IB		Installed Base		
SOP	High	P-IS	01	Installation and Servicing incl. returned goods		
Work instruction		W-DG	01	Decontaminate goods		
Template		T-SLS	see SOP	Service Log Sheet		
Template		T-SIS	see SOP	Service Instruction Spec		
Template		T-SIR	see SOP	Service Instruction Report		
Template		T-SAG	see SOP	Service Agreement		
SOP	Medium	P-PT	01	Product Training		
Template		T-PTC	see SOP	Product Training Certificate form (TC)		
Template		T-PTR	see SOP	Product Training Record		
SOP	Medium	P-PMS	01	Post Market Surveillance		
Template		T-PMSP	see SOP	PMS plan (including PMCF)		
Template		T-PSUR	see SOP	PSUR report (including PMCF)		
SOP	High	P-CH	01	Complaint Handling		
Template		T-CO	see SOP	Complaint form		
SOP	Medium	P-RA	01	Regulatory Affairs		
Template		T-STD	see SOP	Summary Technical Documentation		
Template		T-GSPR	see SOP	General Safety and Performance Requirements MDR Compliance Report		
Template		T-EHSR	see SOP	Essential Health and Safety Requirements Machinery Directive Compliance Report		
Template		T-ERER	see SOP	Essential Requirements EMC Directive Compliance Report		
Template		T-DOC	see SOP	Declaration of Conformity		
SOP	Medium	P-FSCA	01	Field Safety Corrective Action		
SOP	Medium	P-VI	01	Vigilance		
SOP	High	P-PCM	01	Product Change Management		
Template		T-PCR	see SOP	Product Change Request form		
Process	Medium	SC		Supplier Control		
SOP	Medium	P-SS	01	Supplier Selection, Approval and Performance		
Template		T-SSF	see SOP	Supplier Selection form		
Template		T-SEF	see SOP	Supplier Evaluation form		
Template		T-MQA	see SOP	Manufacturing Quality Agreement		
Template		T-DQA	see SOP	Development Quality Agreement		
SOP	Medium	P-PU	01	Purchase and Incoming inspection		
Template		T-PO	see SOP	Purchase order		
Process	Medium	SS		Sales and Service		
SOP	Low	P-DS	01	Distributor Selection and Control		
Template		T-DS	see SOP	Distributor Selection		
Template		T-DA	see SOP	Distributor agreement		
SOP	Medium	P-HI	01	Handling incoming orders		
Process	Medium	RM		Resource Management		
SOP	Medium	P-HR	01	Human Resource Competences and Qualification		
Template		T-SM	see SOP	Staff Matrix		
Template		T-AFTP	see SOP	Appraisal form and training program		
Template		T-TRCL	see SOP	Training Record Classroom		

Template		T-TRRU	see SOP	Training Record Read and Understood		
Template		T-TROI	see SOP	Training Record Only Inform		
Template		T-NSC	see SOP	New Staff Checklist form		
SOP	Low	P-LE	TBD	Legal		
Template		T-CT	see SOP	Contract Amendment		
Template		T-NDA	see SOP	Non Disclosure Agreement		
SOP	Medium	P-EC	01	Equipment Control		
Template		T-EVSR	see SOP	Equipment Verification Spec / Report		
SOP	Medium	P-STV	01	Software Tool Validation		
Template		T-TVR	see SOP	Tool Validation Report		
SOP	Medium	P-IE	01	Infrastructure, Environment Control and Product Identification		
Annex		T-CFP	01	Company floor plan		
Work instruction		W-PI	01	Product Infrastructure, Inspection and Storage		
Template		T-CPI	see SOP	Customer Property Index		
Template		T-PCL	see SOP	Pest Control Logbook		
Template		T-RIE	see SOP	RlandE Analysis		
SOP	Medium	P-DG	01	Data protection policy and GDPR		
Template		T-ROP	see SOP	Register of processing activities		
Template		T-ECF	see SOP	Employee consent form		
Template		T-PCF	see SOP	Participant consent form		
Annex		T-PCFS	01	Participant consent form statement		
Annex		T-PRP	01	Privacy policy		
SOP	Medium	P-DBR	01	Data Breach Response		
Template		T-DBR	see SOP	Data breach register		