## IEC 62304:2006 Mapping of Requirements to Documents

This table maps all requirements of the IEC 62304:2006 (by section) to the relevant documents (here: OpenRegulatory templates).

Note that the document names in the "Fulfilled in Document" column are based on the OpenRegulatory templates. You'll probably have a different system for assigning document names, so feel free to rename them.

ClasseSectioFittle (General) Quality management system		ioThitle	Fulfilled in Document	Comment	
			Quality Management Manual		
	4.2	Risk management	SOP Integrated Software Development		
	4.3	Software Safety Classification	Risk Management Report		
	4.4	Legacy Software	(Not applicable)	Not applicable unless you have legacy software.	
А, В, С	5.1.1	Software development plan	Software Development and Maintenance Plan	·	
А, В, С	5.1.2	2 Keep software development plan update	SOP Integrated Software Development		
A, B, C	5.1.3	Software development plan reference to system design and development	Software Development and Maintenance Plan		
С	5.1.4	Software development standards, methods and tool planning	Software Development and Maintenance Plan		
В, С	5.1.5	Software integration and integration test planning	Software Development and Maintenance Plan		
А, В, С	5.1.6	Software verification planning	Software Development and Maintenance Plan		

Clas	seSectionitle	Fulfilled in Document	Comment
A, B, C	5.1.7 Software risk management	Software Development and Maintenance Plan	
A, B, C	planning 5.1.8 Documentation planning	Software Development and Maintenance Plan	
A, B, C	5.1.9 Software configuration management planning	Software Development and Maintenance Plan	
В, С В, С	5.1.10Supporting items to be controlled 5.1.11Software configuration item	Software Development and Maintenance Plan Software Development and Maintenance Plan	
В,	control before verification 5.1.12Identification and avoidance of common software defects	Software Development and Maintenance Plan	
А, В, С	5.2.1 Define and document software requirements from	SOP Integrated Software Development; Software Requirements List	
А, В, С	system requirements 5.2.2 Software requirements content	Software Requirements List	
В, С	5.2.3 Include risk control measures in software requirements	Software Requirements List	
А, В, С	5.2.4 Re-evaluate medical device risk analysis	SOP Integrated Software Development	
А, В, С	5.2.5 Update requirements	SOP Integrated Software Development	
А, В, С	5.2.6 Verify software requirements	SOP Integrated Software Development; Checklist Software Requirements	
В, С	5.3.1 Transform software requirements into an architecture	SOP Integrated Software Development; (Software architecture diagrams, interface documentation)	

Clas	seSectionitle	Fulfilled in Document	Comment
В, С	5.3.2 Develop an architecture for the interfaces of software items	SOP Integrated Software Development; (Software architecture diagrams, interface documentation)	
В,	5.3.3 Specify functional and performance requirements of SOUP item	SOUP list	
В,	5.3.4 Specify system hardware and software required by SOUP item	SOUP list	
С	5.3.5 Identify segregation necessary for risk control	SOP Integrated Software Development	
В,	5.3.6 Verify software architecture	SOP Integrated Software Development; Checklist Software Architecture	
В,	5.4.1 Subdivide software into software units	SOP Integrated Software Development; (Software architecture diagrams)	
С	5.4.2 Develop detailed design for each software unit	SOP Integrated Software Development	
С	5.4.3 Develop detailed design for interfaces	SOP Integrated Software Development	
С	5.4.4 Verify detailed design	SOP Integrated Software Development	
А, В, С	5.5.1 Implement each software unit	SOP Integrated Software Development; (GitHub Pull Requests / GitLab Merge Requests)	
В, С	5.5.2 Establish software unit verification process	SOP Integrated Software Development	
В, С	5.5.3 Software unit acceptance criteria	SOP Integrated Software Development	
Č	5.5.4 Additional software unit acceptance criteria	SOP Integrated Software Development	
В,	5.5.5 Software unit verification	SOP Integrated Software Development; (CI/CD in GitHub Pull Requests / GitLab Merge Requests)	

Clas	sseSectionitle	Fulfilled in Document Comment	
В, С	5.6.1 Integrate software units	SOP Integrated Software Development; (Merge in	
C	umus	GitHub / GitLab)	
В,	5.6.2 Verify software	SOP Integrated Software	
C,	integration	Development; (Merge in	
		GitHub / GitLab)	
В,	5.6.3 Software integration	SOP Integrated Software	
С	testing	Development; (Merge in	
		GitHub / GitLab, CI/CD)	
В,	5.6.4 Software integration	SOP Integrated Software	
С	testing content	Development; (CI/CD in	
		GitHub Pull Requests /	
В,	5.6.5 Evaluate software	GitLab Merge Requests) SOP Integrated Software	
С,	integration test	Development	
O	procedures	Bevelopment	
В,	5.6.6 Conduct regression	SOP Integrated Software	
$\mathbf{C}^{'}$	tests	Development; (CI/CD in	
		GitHub Pull Requests /	
		GitLab Merge Requests)	
В,	5.6.7 Integration test	SOP Integrated Software	
С	record contents	Development; (CI/CD in	
		GitHub Pull Requests /	
D	5.6.8 Use software	GitLab Merge Requests) SOP Software Problem	
В, С	problem resolution	Resolution	
O	process	resolution	
A,	5.7.3 Retest after changes	SOP Integrated Software	
В,		Development	
С			
A,	5.7.4 Evaluate software	SOP Integrated Software	
В, С	system testing	Development; Software	
A,	5.7.5 Software system test	System Test Plan SOP Integrated Software	
В,	record contents	Development; Software	
Д, С	receita contentes	System Test Protocol	
Ă,	5.8.1 Ensure software	SOP Integrated Software	
В,	verification is	Development; Checklist	
$\mathbf{C}$	$\operatorname{complete}$	Software Release	
Α,	5.8.2 Document known	SOP Integrated Software	
В,	residual anomalies	Development; (Release	
С		notes / changelog)	
В,	5.8.3 Evaluate known	Risk table; (Release notes /	
С	residual anomalies	changelog)	

ClasseSectionitle			Fulfilled in Document	Comment
A,	5.8.4	1 Document released	SOP Integrated Software	
В,		versions	Development; (Release	
С			notes / changelog)	
В,	5.8.5	5 Document how	SOP Integrated Software	
С		released software	Development; (Release	
D	500	was created  Ensure activities	notes / changelog)	
В, С	5.6.0	and tasks are	SOP Integrated Software Development; Checklist	
C		complete	Software Release	
A,	5.87	7 Archive software	SOP Integrated Software	
В,	0.0.	THEMITY BOTOWARD	Development; (Tagged	
С, С			commit in git)	
Ā,	5.8.8	8 Assure reliable	SOP Integrated Software	
В,		delivery of released	Development	
$\mathbf{C}$		software		
A,	6.1	Establish a software	Software Development and	
В,		maintenance plan	Maintenance Plan	
$\mathbf{C}$				
Α,	6.2.1	I.Monitor feedback		
В,				
C	0.0.1	1.40		
A,	6.2	1. <b>D</b> ocument and evaluate feedback		
В, С		evaruate feedback		
A,	6.2.1	l. <b>E</b> valuate problem	SOP Problem Resolution	
В,	0.2.	report's affects on	SOI TIOSICIII IQOSOIUIIOII	
Д, С		safety		
Ă,	6.2.2	2 Use software	SOP Problem Resolution	
В,		problem resolution		
$\mathbf{C}$		process		
A,	6.2.3	3 Analyse change	SOP Change Management	
В,		requests		
$\mathbf{C}$				
Α,	6.2.4	4 Change request	SOP Change Management	
В,		approval		
$C_{\Lambda}$	601	Communicata ta	COD Change Manager	
А, В,	0.2.	5 Communicate to users and regulators	SOP Change Management	
Б, С		users and regulators		
A,	6.3.1	Use established	SOP Change Management	
В,	0.0.1	process to	201 Change management	
Д, С		implement		
		modification		

Clas	sseSectionitle	Fulfilled in Document	Comment
А, В, С	6.3.2 Re-release modified software system	SOP Change Management	
В, С	7.1.1 Identify software items that could contribute to a hazardous situation	SOP Integrated Software Development	
В, С	7.1.2 Identify potential causes of contribution to a hazardous situation	SOP Integrated Software Development	
В, С	7.1.3 Evaluate published SOUP anomaly lists	SOP Integrated Software Development	
В, С	7.1.4 Document potential causes	SOP Integrated Software Development	
В, С	7.2.1 Define risk control measures	SOP Integrated Software Development	
В, С	7.2.2 Risk control measures implemented in software	SOP Integrated Software Development	
В, С	7.3.1 Verify risk control measures 7.3.2 (Not used)	SOP Integrated Software Development	
В, С	7.3.3 Document traceability	SOP Integrated Software Development; Software Requirements List	
А, В, С	7.4.1 Analyse changes to medical device software with respect to safety	SOP Change Management	
В, С	7.4.2 Analyse impact of software changes on existing risk control measures	SOP Change Management	
В, С	7.4.3 Perform risk management activities based on analyses	SOP Change Management	
А, В, С	8.1.1 Establish means to identify configuration items	Software Development and Maintenance Plan	

ClasseSectioTitle		dhitle	Fulfilled in Document	Comment
A, B, C	8.1.2	Identify SOUP	SOP Integrated Software Development	
А, В, С	8.1.3	Identify system configuration documentation	SOP Integrated Software Development	
А, В, С	8.2.1	Approve change requests	SOP Change Management	
А, В, С	8.2.2	Implement changes	SOP Change Management	
А, В, С	8.2.3	Verify changes	SOP Change Management	
А, В, С	8.2.4	Provide means for traceability of change	SOP Change Management	
А, В, С	8.3	Configuration status accounting	Software Development and Maintenance Plan	
А, В, С	9.1	Prepare problem reports	SOP Software Problem Resolution	
А, В, С	9.2	Investigate the problem	SOP Software Problem Resolution	
А, В, С	9.3	Advise relevant parties	SOP Software Problem Resolution; SOP Incident Reporting	
А, В, С	9.4	Use change control process	SOP Change Management	
A, B, C	9.5	Maintain records	SOP Software Problem Resolution	
A, B, C	9.6	Analyse problems for trends	SOP Software Problem Resolution	
A, B, C	9.7	Verify software problem resolution	SOP Software Problem Resolution	

ClasseSectionitle			Fulfilled in Document	Comment
A, B, C	9.8	Test documentation contents	SOP Integrated Software Development	

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