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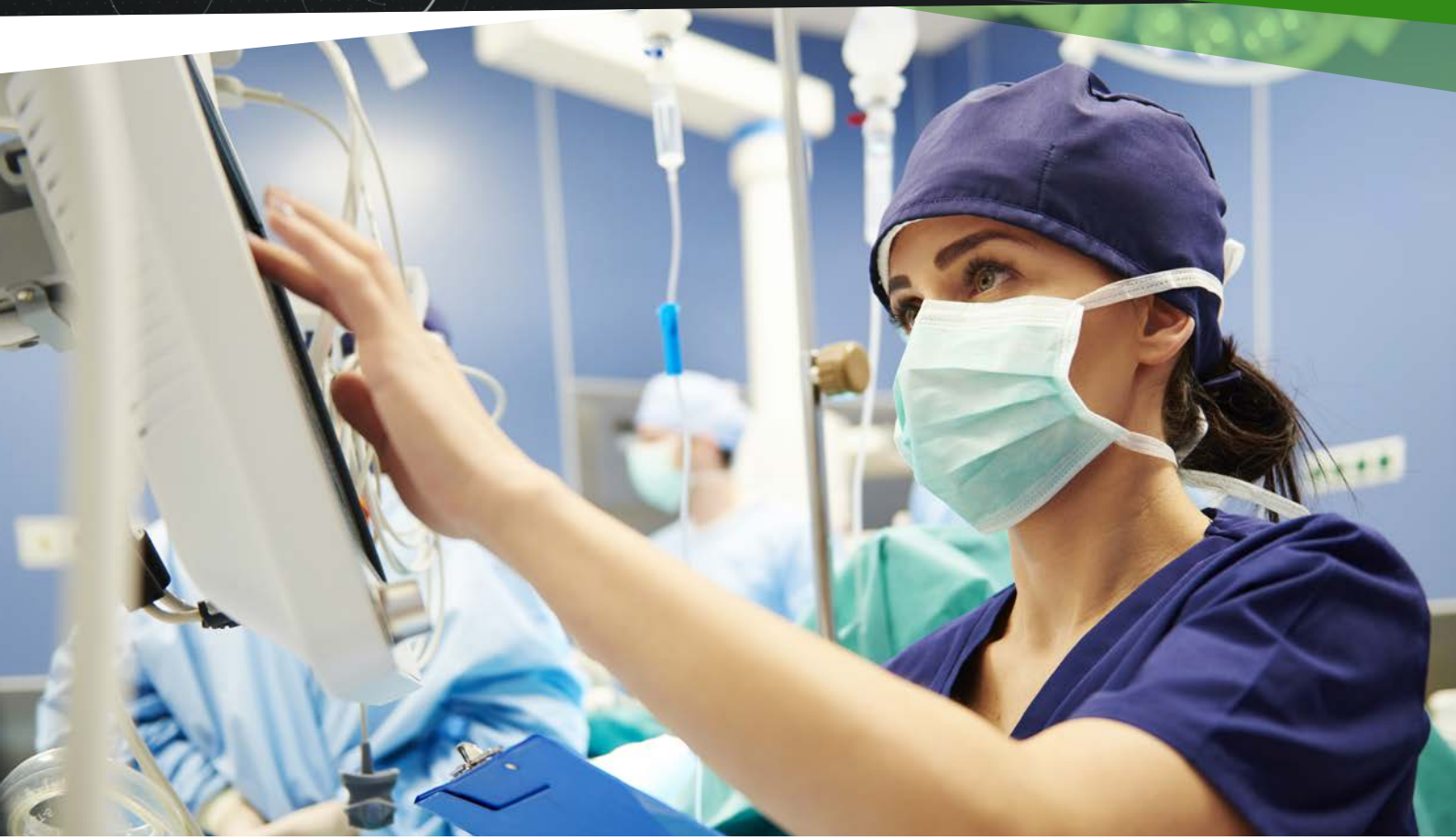
DIGITAL TRANSFORMS PHYSICAL

Medical Software Engineering Template

Compliance support for EU MDR and US FDA regulations and applicable standards: IEC 82304-1, IEC 62304, ISO 14971, and FDA T21 CFR Part 11 & 820



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The Medical Software Engineering Template

As a developer of medical technology, you are likely facing a twofold challenge in today's digital healthcare economy. On one hand, due to increasing regulatory scrutiny, you need to enhance the quality of your products (as well as overall organizational excellence). Market pressure from competitors, on the other hand, pushes you to increase your speed of product delivery. Established best practices are immensely valuable in connecting and achieving those goals in the development of medical technology.

This **Medical Software Engineering Template** enables you to adopt best practices for medical software development with minimal effort. This template contains baked-in domain knowledge and processes that leverage industry best practices, inherently providing conformance to regulatory requirements in the European Union and United States markets.

In addition to being predefined for regulatory compliance, this template provides user-focused and practical information to walk users through a fully compliant delivery process for medical technology software. The template's wiki, artifacts, processes, and documents may be easily understood through the example of a glucose meter development project demonstrated in this template.

SCOPE

This Medical Software Engineering Template focuses on:

- **Medical software development for software as a stand-alone medical device**
- **Software as part of an embedded system**
- **Software as a mobile medical application**

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Why use this Medical Software Engineering Template?

Streamline compliance with regulatory requirements in the development of medical devices & digital healthcare technology.

1

Fully customizable
Adapt preconfigured artifacts and processes to your needs. Customize the template for a tailor-made solution for development support and compliance.

2

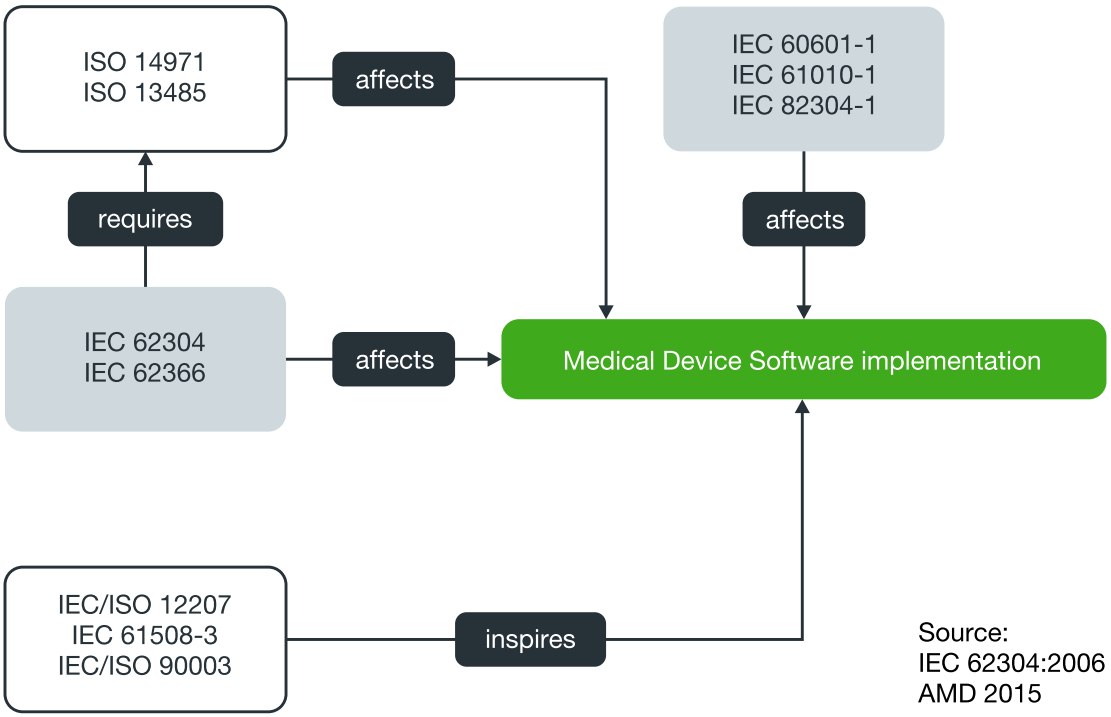
Shorter route to value
Use this template out of the box to implement a fully compliant development project. Reduce effort, costs, and time to market.

3

Medical compliance
Use an all-in-one hub to manage all your technical content for CE marking & US FDA market access reviews. Rely on compliance support for EU MDR/ IVDR (Class I to III), IEC 62304, ISO14971, ISO 13485, FDA Title 21 CFR Part 11 & Part 820, IEC 82304-1.

4

Integrated quality management
Automate process control in medical software development to avoid deviations. Connect quality control and audit management using the Medical Audit & CAPA Template.

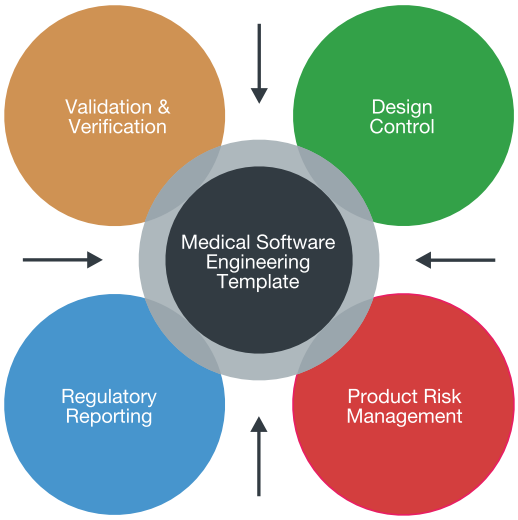


Source:
IEC 62304:2006
AMD 2015

Capabilities of the Medical Software Engineering Template

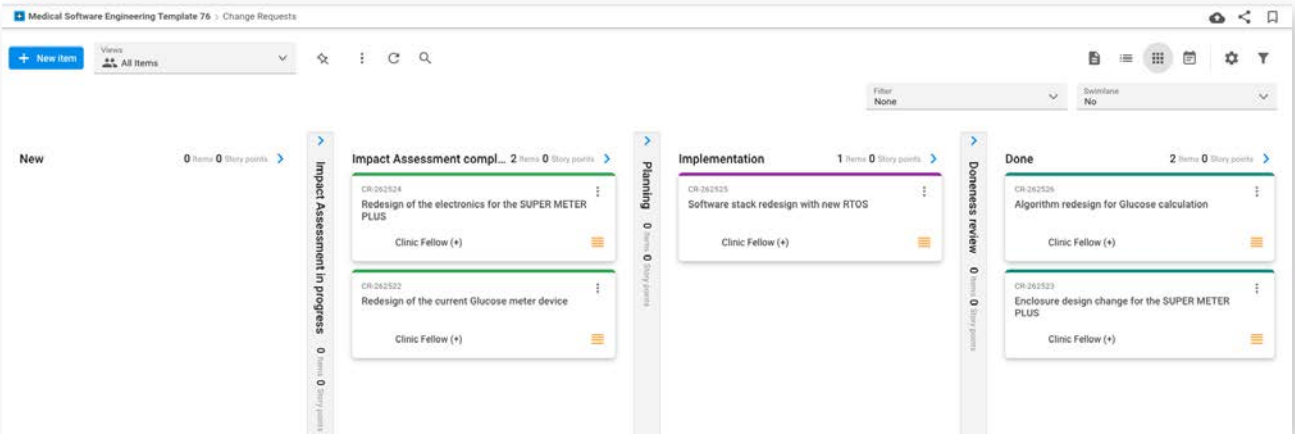
Requirements Engineering

Requirements Engineering is an integrated part of this Medical Software Engineering Template. You'll find predefined artifacts to manage product architecture, user requirements, system requirements, design specifications, and more. The template lets you manage product risk-related requirements on multiple levels, including non-software related items (such as packaging and labeling requirements). All these requirements are interconnected with references to guarantee traceability.



Change Management

Once you have an approved budget, feature development can start. To support transparent development in an Agile setting, this template provides Change Requests artifacts. By default, these items may be easily referenced to Planned Product Releases, Tasks, or User Requirements – but you can easily adapt these relations to your needs. Change Request items also provide data fields for product risk impact assessment. Any and all changes on all your work items are automatically recorded and may be reviewed at any time.



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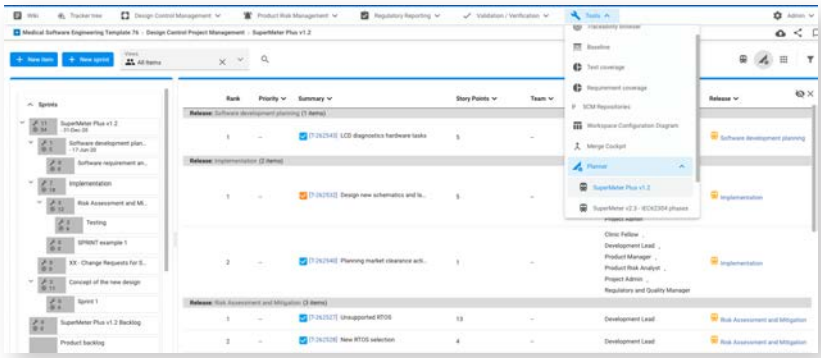
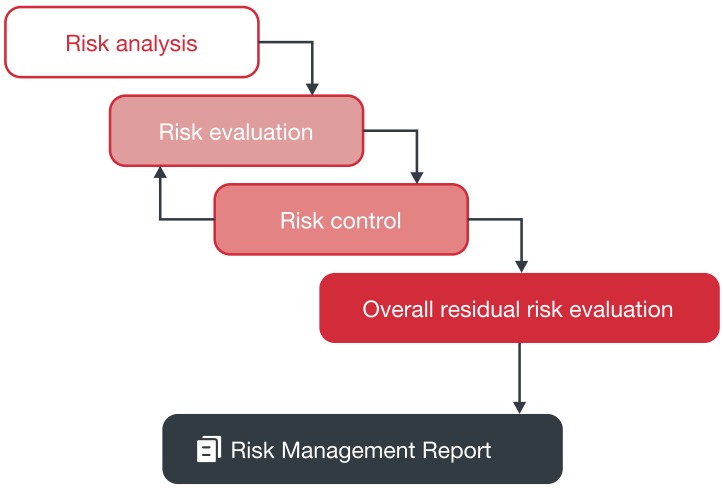
Support from Development to Release

This Medical Software Engineering Template supports an integrated approach to medical software development. End-to-end traceability is easily achieved, and you can simply compile custom traceability queries in the Traceability Browser. Predefined queries help you answer typical traceability-related questions with minimal effort. Using this template, you can manage the development of medical software (including risks) from idea all the way to release while complying with the information and process requirements of IEC 62304:2006 with its latest (2015) amendments, IEC 82304-1, and ISO 14971:2012.





Lifecycle Product Risk Management

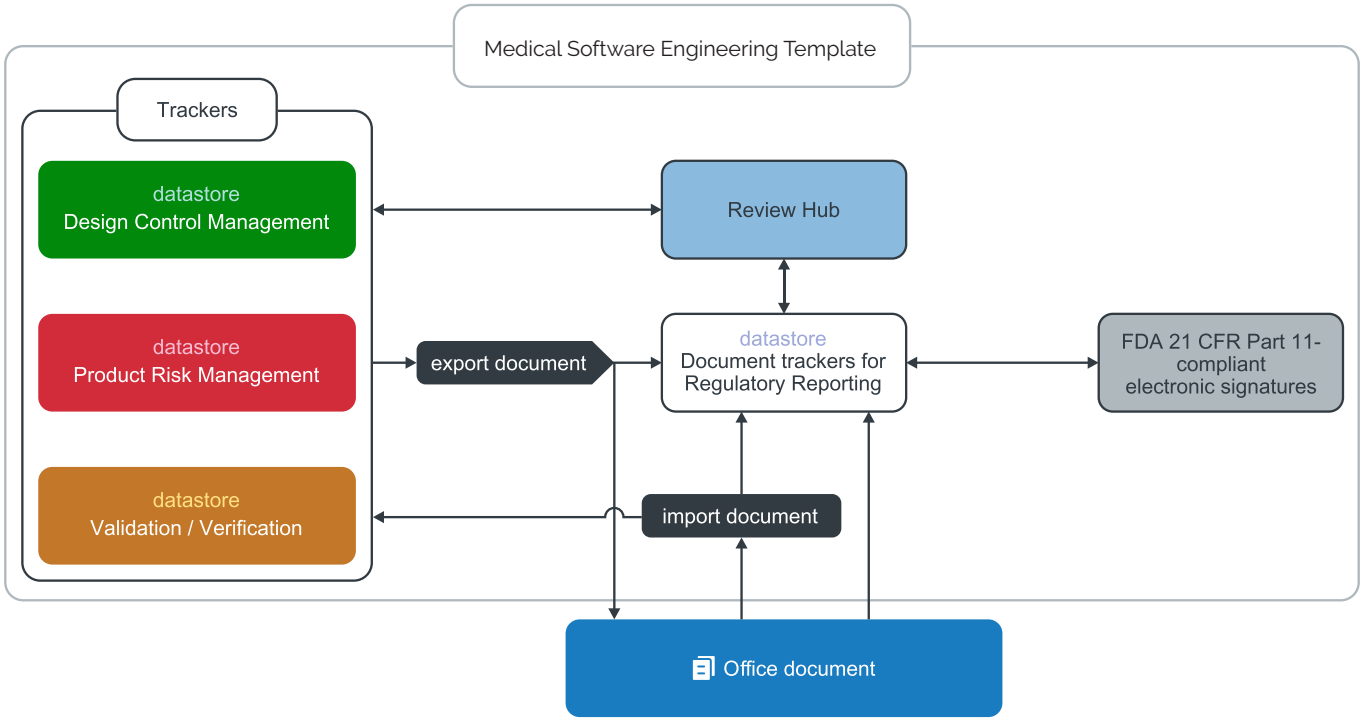
This template helps your product risk management activities throughout the entire medical software development lifecycle as per the normative part of ISO 14971. You can easily record, manage, and track risks, and associate them to other work items for risk traceability. Risk-related data may be stored in dedicated trackers, including risk analysis information and "information access" data. You can manage risks together with risk control measures to enable insights into the overall risk levels of your products.

Documentation Management

Using configurable export templates, you can easily export all data stored in the Design Control, Product Risk Management, and Verification and Validation artifacts to Office documents. Similarly, content stored externally in documents may be easily imported into trackers. You can rely on sophisticated review processes for your documents using the Review Hub, and timestamped, Part 11-compliant e-signatures may be used for the review & approval for all items including documents.

Technical File & Design History File

This Medical Software Engineering Template supports the compilation of a Technical File or a Design History File. Any and all engineering content and processes (entered, maintained, or archived in the system) can be simply collected and organized to produce a comprehensive Technical File or DHF. You can also easily incorporate external content into these repositories, and verify them with compliant electronic signatures. Any information stored outside of this template may be easily imported.



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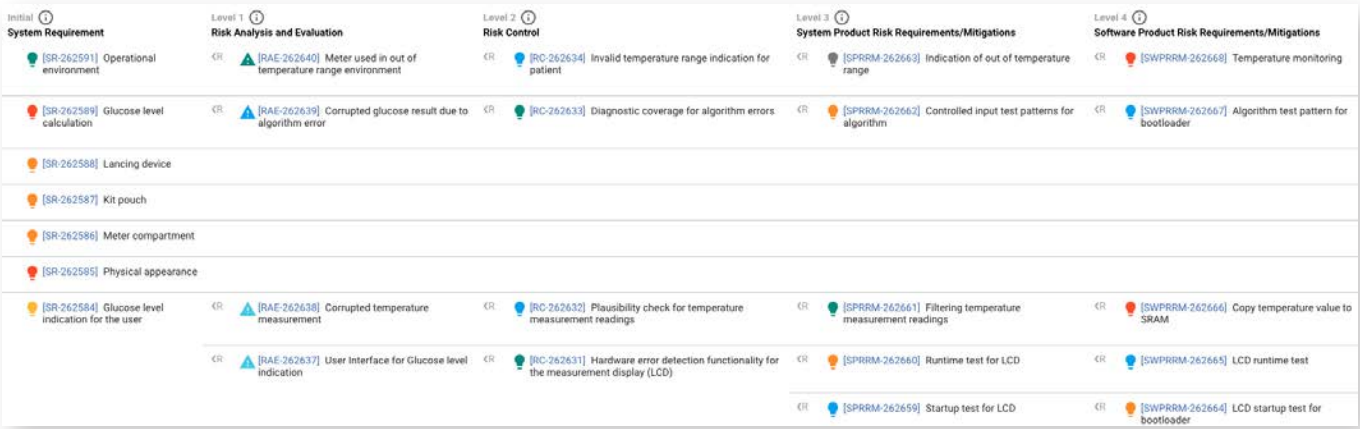
Design Control

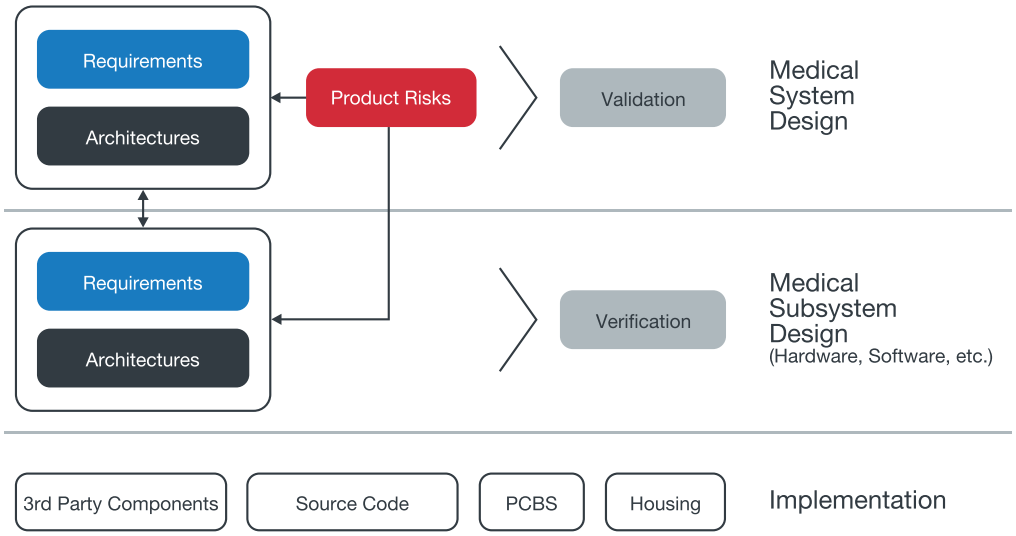
The Medical Software Engineering Template was developed to support the lifecycle-wide design control processes of MedTech software. You can easily integrate organization-specific practices into this template, enabling medical software development organizations to tailor the template to their needs. Processes may be enforced via guards, e-signatures, and other workflow practices to avoid deviations.

Verification & Validation

This template supports effective, traceable, and reportable product verification and validation activities. Predefined protocols, test data, and established relationships between items help you manage verification and validation on multiple levels. Artifacts are available for system validation, software-hardware verification integration, software unit verification etc, with traceability guaranteed across them.



Initial System Requirement	Level 1 Risk Analysis and Evaluation	Level 2 Risk Control	Level 3 System Product Risk Requirements/Mitigations	Level 4 Software Product Risk Requirements/Mitigations
[SR-262591] Operational environment	[RAE-262640] Meter used in out of temperature range environment	[RC-262634] Invalid temperature range indication for patient	[SPRRM-262663] Indication of out of temperature range	[SWPRRM-262668] Temperature monitoring
[SR-262589] Glucose level calculation	[RAE-262639] Corrupted glucose result due to algorithm error	[RC-262633] Diagnostic coverage for algorithm errors	[SPRRM-262662] Controlled input test patterns for algorithm	[SWPRRM-262667] Algorithm test pattern for bootloader
[SR-262588] Lancing device				
[SR-262587] Kit pouch				
[SR-262586] Meter compartment				
[SR-262585] Physical appearance				
[SR-262584] Glucose level indication for the user	[RAE-262638] Corrupted temperature measurement	[RC-262632] Plausibility check for temperature measurement readings	[SPRRM-262661] Filtering temperature measurement readings	[SWPRRM-262666] Copy temperature value to SRAM
	[RAE-262637] User Interface for Glucose level indication	[RC-262631] Hardware error detection functionality for the measurement display (LCD)	[SPRRM-262660] Runtime test for LCD	[SWPRRM-262665] LCD runtime test
			[SPRRM-262659] Startup test for LCD	[SWPRRM-262664] LCD startup test for bootloader



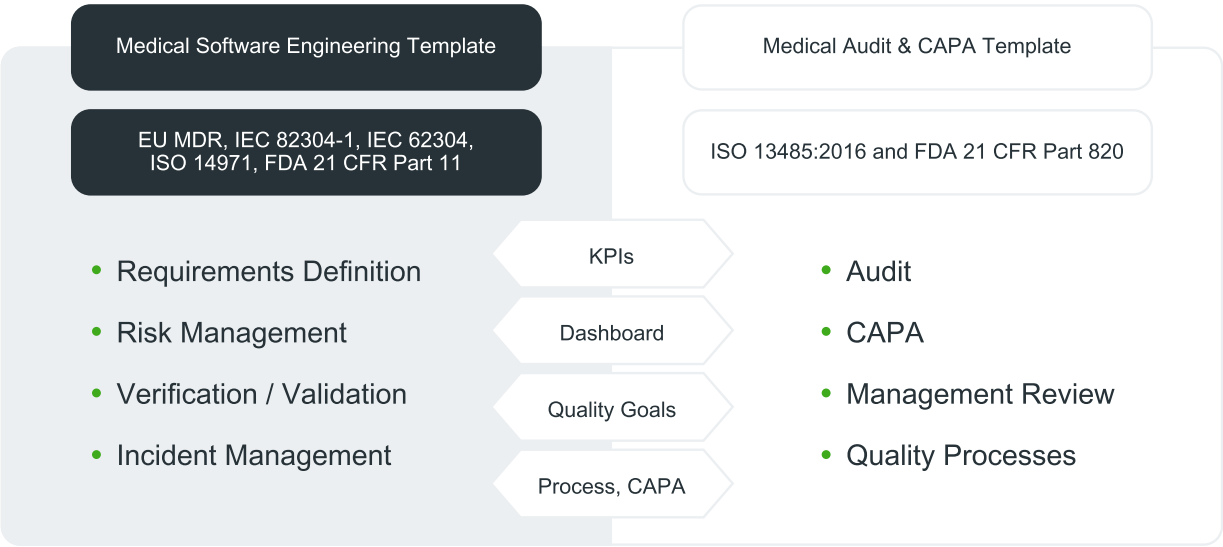
Vigilance and Post-Market Surveillance

To help you adhere to the requirements of EU MDR's Annex III on Post-Market Surveillance, this template provides a dedicated information container. Market recall and adverse incident reports from the US FDA and EU Local Authorities can easily be imported to provide a solid foundation for market vigilance and market surveillance activities. Pro tip: Codebeamer's Medical Audit & CAPA Template takes this even a step further, offering Customer Complaint and Feedbacks, CAPA content, and Adverse Incident Reporting.

SOUP and Legacy Software Management

The standard IEC 62304:2006/AMD1:2015 distinguishes between two types of externally sourced software used in medical software development: Software Of Unknown Provenance (SOUP) and Legacy Software. This template provides dedicated information containers and preset traceability rules in its SOUP artifacts to provide compliance evidence. The template also offers preconfigured capability and items to capture information on Legacy Software in order to support compliance with the measures, considerations, and requirements set forth by IEC 62304:2006/AMD1:2015.

Quality Management for Medical Devices



	Intland's built-in functionality								
	Trackers	Configuration Items	Wiki	Document Management	SCM Repositories	Reports	Traceability Browser	V&V Management	Roadmap Manager
IEC 82304-1:2016 : Health software – Part 1: General requirements for product safety									
Health Software Product Requirements									
General requirements and initial Risk Assessment	+	+	+	+		+	+	+	+
Health Software Product use requirements	+	+		+		+		+	
Verification of Health Software Product use requirements	+	+		+		+			
Updating Health Software Product use requirements	+	+		+		+	+		
System requirements	+	+		+		+			
Verification of system requirements	+	+		+		+	+	+	
Updating Health Software Product system requirements	+	+		+		+	+		
Health Software – Software Life Cycle Processes	See evaluation for IEC 62304:2006								
Health Software Product Validation									
Validation plan			+	+					
Performing validation							+	+	+
Validation report				+		+			
Health Software Product Identification and Accompanying Documents									
Identification	+	+		+	+				+
Instructions for use				+					
Technical description				+					
Post-market Activities for the Health Software Product									
Software Maintenance			+	+	+				+
Re-validation				+		+	+	+	+
Post-market communication on the Health Software Product	+	+		+					
Decommissioning and disposal of the Health Software Product				+		+			
IEC 62304:2006 : Medical device software - Software life cycle processes									
General Requirements									
Quality management system			+	+		+			
Risk Management	+	+	+	+	+	+	+	+	+
Software safety classification			+	+					
Software Development Process									
Software development planning			+	+					+
Software requirements analysis	+	+				+	+		
Software architectural design	+	+					+		
Software detailed design	+	+					+		
Software unit implementation and verification	+	+			+		+	+	+
Software integration and integration testing	+	+					+	+	
Software system testing	+	+					+	+	+
Software release				+	+	+			+
Software Maintenance Process									
Establish software maintenance plan			+	+					
Problem and modification analysis						+	+		
Modification implementation	+	+					+	+	+
Software Risk Management process									
Analysis of software contributing to hazardous situations	+	+				+	+		
Risk Control measures	+	+				+	+		
Verification of Risk Control measures	+	+				+	+	+	
Risk Management of software changes	+	+				+	+		+
Software configuration management process									
Configuration identification	+	+	+	+	+				
Change control	+	+					+		+
Configuration status accounting				+	+				
Software problem resolution Process									
Prepare problem reports	+	+				+			
Investigate the problem	+	+					+	+	
Advise relevant parties	+	+							
Use change control process			+	+	+				+
Maintain records	+	+	+	+					
Analyse problems for trends	+	+					+	+	
Verify software problem resolution							+	+	
Test documentation contents	+	+	+	+				+	
EN ISO 14971:2012 : Medical devices — Application of risk management to medical devices									
General requirements for risk management									
Risk management process	+	+	+	+					+
Management responsibilities			+	+					
Qualification of personnel			+	+					
Risk management plan			+	+					
Risk management file	+	+		+		+	+	+	+
Risk analysis									
Risk analysis process	+	+		+					+
Intended use and identification of characteristics related to the	+	+		+					
Identification of hazards	+	+		+					
Estimation of the risk(s) for each hazardous situation	+	+		+					
Risk evaluation	+	+		+					+
Risk control									
Risk reduction	+	+				+			
Risk control option analysis	+	+				+			
Implementation of risk control measure(s)	+	+				+			
Residual risk evaluation	+	+				+			
Risk/benefit analysis	+	+		+		+			
Risks arising from risk control measures	+	+				+	+	+	
Completeness of risk control	+	+			+	+	+	+	
Evaluation of overall residual risk acceptability	+	+		+		+	+		

Templates

Start quickly and accelerate your ROI using preconfigured templates. Templates are easy to use, and you can adapt them flexibly to suit your organization's individual needs.

- Document Management Template
- ISO 9001:2015 QMS Template
- Requirements Management Template
- Scrum Agile Template
- Test Management Template
- Customer Support Template
- **Medical Software Engineering Template**
- **Medical Audit & CAPA Template**
- Pharma GAMP®5 Template
- SAFe® Template
- Customer Relationship Management (CRM) Template
- Agile Marketing Template

Download our Medtronic case study to learn how the world's largest medical technology company reaches compliance in a scaled Agile development environment

Medtronic

Integrations

Connect your fragmented tool environment in a central development platform through out-of-the-box integrations. Reduce hidden costs and the tedious manual work of creating integrations. Enjoy full traceability and data consistency, and slash tool maintenance costs.

JUnit
eclipse
Jenkins
APACHE JMeter™
RED HAT OPENSHIFT
CANTATA
ENTERPRISE ARCHITECT
ReqIF
Quality Center
kubernetes
DOORS
plasticscm
TeamCity
VECTOR
git
GitLab
MATLAB SIMULINK
GitHub

Our solutions are successfully used by:

Medtronic
SAMSUNG
Inivata
STEPHAN
NewYork-Presbyterian
sysmex
medin A Hamilton Medical Company
Rakuten Medical
COSYLAB
TrakCel
MicroDiscovery
bigfoot BIOMEDICAL
spōk
DITABIS DIGITAL BIOMEDICAL IMAGING SYSTEMS AG

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Validation Kits

Codebeamer's Validation Kits are valuable tools for safety-critical product development teams with regulatory compliance needs.

- **Tool Validation Kit**
  Use this kit to simplify and accelerate tool qualification and validation in regulated product development.
- **Title 21 CFR Part 11 Validation Kit**
  Rely on this tool to prove compliance with 21CFR11 requirements about electronic records management.