



Document Management Plan

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Andersen Site

Revision History



Date	Version	Description of change	Author	Approved Name	Approved Date
08.11.2022	0.1	Initial version	Andrei Belski		
08.11.2022	1.0	Effective	Andrei Belski	Jim Hopkins	08.11.2022

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Roles and Responsibilities



The following abbreviations are used to define the roles: R – responsible, A – accountable, C – consulted, I – informed, N/A – not applicable, TBA – to be added.

#		1	2	3	4	5
Artifact	Title	Document Management Plan (current document)	Project Management Plan	Software Development Plan	Traceability Analysis	Vision and Scope
	Version	3.0	1.1	1.0	2.0	2.0
	Document ID	AS.HP.PP.01	AS.HP.PP.02	AS.HP.PP.03	AS.HP.PD.01	AS.HP.PD.02
Responsible/ Author		Andrei Belski	Illya Kangin	Javidan Hatamov	Tatsiana Barada	Tatsiana Barada
Accountable/ Reviewer		Illya Kangin	Andrei Belski	Andrei Belski	Andrei Belski	Andrei Belski
Consulted		N/A	N/A	Roman Tov	N/A	N/A
Informed		N/A	N/A	N/A	N/A	N/A
Customer Approver		Customer representative	Customer representative	Customer representative	Customer representative	Customer representative
Status		In progress	In progress	Approved	Under review	Approved
Evidence/Link/ Comments		Current document	AS.HP.PP.02 Project Management Plan	AS.HP.PP.03 Software Development Plan	AS.HP.PD.01 Traceability Analysis	AS.HP.PD.02 Vision and Scope
Document Delivery (Milestone/ Phase/Date)		MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022

Roles and Responsibilities



#		6	7	8	9	10
Artifact	Title	Business Requirements Document	Software Requirements Specification	Software Specification Review	Software Architecture Document	Software Design Document
	Version	2.0	1.0	1.0	2.0	2.0
	Document ID	AS.HP.PD.03	AS.HP.PD.04	AS.HP.PR.01	AS.HP.PD.05	AS.HP.PD.06
Responsible/ Author		Tatsiana Barada	Tatsiana Barada	Tatsiana Barada	Roman Tov	Elena Tatarava
Accountable/ Reviewer		Andrei Belski	Andrei Belski	Andrei Belski	Andrei Belski	Andrei Belski
Consulted		N/A	N/A	N/A	N/A	Roman Tov
Informed		N/A	N/A	N/A	N/A	N/A
Customer Approver		Customer representative	Customer representative	Customer representative	Customer representative	Customer representative
Status		Approved	Approved	Approved	Under review	In progress
Evidence/Link/ Comments		AS.HP.PD.03 Business Requirements Document	AS.HP.PD.04 Software Requirements Specification	AS.HP.PP.03 Software Development Plan	AS.HP.PD.01 Traceability Analysis	AS.HP.PD.02 Vision and Scope
Document Delivery (Milestone/ Phase/Date)		MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022

Roles and Responsibilities



#		11	12	13	14	15
Artifact	Title	Validation Plan	Validation Report	Test Plan	Test Cases	Test Report
	Version	1.0	0.3	1.0	2.0	1.0
	Document ID	AS.HP.PD.06	AS.HP.PR.02	AS.HP.PR.05	AS.HP.PD.06	AS.HP.PD.05
Responsible/ Author		Pavel Kardakov	Pavel Kardakov	Pavel Kardakov	Pavel Kardakov	Pavel Kardakov
Accountable/ Reviewer		Andrei Belski	Andrei Belski	Andrei Belski	Andrei Belski	Andrei Belski
Consulted		N/A	N/A	N/A	N/A	Roman Tov
Informed		N/A	N/A	N/A	N/A	N/A
Customer Approver		Customer representative	Customer representative	Customer representative	Customer representative	Customer representative
Status		Approved	In progress	Approved	Approved	Approved
Evidence/Link/ Comments		AS.HP.PD.06 Validation Plan	AS.HP.PR.02 Validation Report	AS.HP.PR.05 Test Plan	AS.HP.PD.06 Test Cases	AS.HP.PD.05 Test Report
Document Delivery (Milestone/ Phase/Date)		MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022

Roles and Responsibilities



#		16	17	18	19	20
Artifact	Title	Release Notes	IT Security Risk Assessment	Problem Management Report	Configuration and Change Management Plan	Change Request Form
	Version	0.1	2.0	1.0	2.0	1.0
	Document ID	AS.HP.PD.07	AS.HP.PD.08	AS.HP.PR.06	AS.HP.PP.07	AS.HP.PD.09
Responsible/ Author		Javidan Hatamov	Andrei Belski	Illya Kangin	Illya Kangin	Andrei Belski
Accountable/ Reviewer		Andrei Belski	Illya Kangin	Andrei Belski	Andrei Belski	Illya Kangin
Consulted		N/A	Roman Tov, Javidan Hatamov	N/A	N/A	Roman Tov
Informed		N/A	N/A	N/A	N/A	N/A
Customer Approver		Customer representative	Customer representative	Customer representative	Customer representative	Customer representative
Status		In progress	In review	Approved	Approved	Approved
Evidence/Link/ Comments		AS.HP.PD.07 Release Notes	AS.HP.PD.08 IT Security Risk Assessment	AS.HP.PR.06 Problem Management Report	AS.HP.PP.07 Configuration and Change Management Plan	AS.HP.PD.09 Change Request Form
Document Delivery (Milestone/ Phase/Date)		MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022

Roles and Responsibilities



#		21	22	23	24	25
Artifact	Title	Software Maintenance Plan	IFU/Manual	Software Tool Validation Plan and Report	Medical Device File	Medical Device File Report
	Version	1.0	1.0	1.0	0.2	0.1
	Document ID	AS.HP.PP.08	AS.HP.PD.10	AS.HP.PP.09	AS.HP.PD.11	AS.LB.PR.06
Responsible/ Author		Javidan Hatamov	Pavel Kardakov	Pavel Kardakov	Andrei Belski	Andrei Belski
Accountable/ Reviewer		Andrei Belski	Andrei Belski	Andrei Belski	Illya Kangin	Illya Kangin
Consulted		Roman Tov	Tatsiana Barada	N/A	Roman Tov	Roman Tov
Informed		N/A	N/A	N/A	N/A	N/A
Customer Approver		Customer representative	Customer representative	Customer representative	Customer representative	Customer representative
Status		Approved	In review	Approved	In progress	In progress
Evidence/Link/ Comments		AS.HP.PP.08 Software Maintenance Plan	AS.HP.PD.10 Instruction for Use	AS.HP.PP.09 Software Tool Validation Plan and Report	AS.HP.PD.11 Medical Device File	AS.LB.PR.06 Medical Device File
Document Delivery (Milestone/ Phase/Date)		MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022

Roles and Responsibilities



#		26	27	28	29
Artifact	Title	Usability Engineering File	Risk Management Plan	Risk Management File	Regulatory Compliance Review
	Version	2.1	1.0	2.0	1.0
	Document ID	AS.LB.PD.12	AS.LB.PP.10	AS.LB.PD.14	AS.LB.PR.07
Responsible/ Author		Andrei Belski	Andrei Belski	Andrei Belski	Andrei Belski
Accountable/ Reviewer		Illya Kangin	Illya Kangin	Illya Kangin	Illya Kangin
Consulted		Roman Tov, Tatsiana Barada	Roman Tov	Roman Tov, Tatsiana Barada, Pavel Kardakov	Roman Tov, Pavel Kardakov
Informed		N/A	N/A	N/A	N/A
Customer Approver		Customer representative	Customer representative	Customer representative	Customer representative
Status		In progress	Approved	Under review	Under review
Evidence/Link/ Comments		AS.LB.PD.12 Usability Engineering File	AS.LB.PP.10 Risk Management Plan	AS.LB.PD.14 Risk Management File	AS.LB.PR.07 Regulatory Compliance Review
Document Delivery (Milestone/ Phase/Date)		MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022	MVP 30-12-2022



The healthcare provider is responsible for the development and handling of the following documentation:

No.	Artifact			Author Reviewer	Status	Evidence/ Link/ Comments
	Title	Version	Document ID			
1	Clinical Evaluation Plan	TBA	TBA	TBA	TBA	TBA
2	Clinical Evaluation Report	TBA	TBA	TBA	TBA	TBA
3	Clinical Evaluation Assessment Report	TBA	TBA	TBA	TBA	TBA
4	Post-Market Clinical Follow-up (PMCF)	TBA	TBA	TBA	TBA	TBA
5	Periodic Safety Update Report (PSUR)	TBA	TBA	TBA	TBA	TBA
6	Deployment Plan	TBA	AS.HP.PP.11	Andrei Belski	Under review	AS.HP.PP.11 Deployment Plan



The document owner (Responsible/Author) creates a document draft in the Word format, then uploads it to Confluence, and invites stakeholders to contribute/review/approve the document via the “Invite to edit” pop-up window.

The screenshot shows a white pop-up window titled "Invite To Edit". At the top, there is a text input field with the placeholder text "Enter name, group, team or email". Below this field is a smaller line of text: "Recipients will see the name of the page and your message". Underneath that is a larger text area with the placeholder "Add a message". At the bottom left, there is a circular icon with a link symbol and the text "Copy link". At the bottom right, there is a blue rectangular button with the white text "Invite".

When the document is approved by the healthcare provider’s representative, the document owner fills in the revision history section and publishes the document in Confluence.

Attention! The document owner must only publish effective/approved versions of the document in Confluence (to control effective versions of the document via the History Page in Confluence). The document can only be published by the document owner.

Document Approval Flow

