Medical Device File

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Revision History

Date	Version	Description of change	Author	Approved Name	Approved Date
04.11.2022	0.1	Initial version	Andrei Belski		
04.11.2022	1.0	Effective	Andrei Belski	Customer representative	04.11.2022

Abbreviations and acronyms

MDF	Medical Device File
DDF	Device and Development File
DMP	Document Management Plan
PMP	Project Management Plan
HA	Healthcare Application
SaMD	Software as a Medical Device

Table of contents

1.1 Introduction

The purpose of this document is to demonstrate the compliance of the device(s) with ISO 13485 requirements, applicable regulatory requirements, and the requirements for design and development and records for design and development changes.

1.2 Scope

The document applies to HA in the framework of the SaMD project.

Content of the Medical Device File (MDF)

Document name	Managed by	Reference	Comments
Device description and specifications			
General Description of the Device	Healthcare provider	AS.HP.PD.02 Vision and Scope AS.HP.PD.11 Usability Engineering File	HA v.1.0 HA is designed to control the process of patient rehabilitation. HA enables physicians to get information or updates about patients undergoing rehabilitation, both stationary and aftercare, related to completing tasks and making progress.
Intended Use	Healthcare provider	AS.HP.PD.02 Vision and Scope AS.HP.PD.11 Usability Engineering File	HA is intended for use by physicians in a clinic in order to: • Create plans for patients; • View information about completed training and training that must be completed, as well as about patient progress; • View available scenarios with exercises for rehabilitation and assign them to patients; • View patient progress and adjust rehabilitation plans if necessary.
Device Classification Statement	Healthcare provider	Healthcare Compliance Preparation Plan	• Class IIa according to MDR; • Class A according to IEC 62304.
Device Specifications	Healthcare provider	AS.HP.PD.02 Vision and Scope AS.HP.PD.03 Business Requirements Document AS.HP.PD.04 Software Requirements Specification AS.HP.PD.05 Software Architecture Document AS.HP.PD.06 Software Design Document	• Vision and Scope; • Business Requirements Document; • Software Requirements Specification; • Software Design Document.

Content of the Medical Device File (MDF)

List of Applicable Standards	Healthcare provider	Quality Agreement	• ISO 13485:2016 • ISO/IEC 27001:2013 • ISO 14971:2019 • IEC 62304:2006/AMD1:2015 • IEC 62366-1:2015 • IEC 82304-1:2016 • IEC 81001-5-1:2021 • MDR • GDPR
Labeling			
Product Labels	Healthcare provider	Requirements for Digital Health Label	Digital health labeling according to MDR
Instructions for Use	Healthcare provider	AS.HP.PD.09 Instructions for Use	Instructions for the use of platform are intended for healthcare personnel
Installation Information	Healthcare provider	AS.HP.11 Deployment Plan AS.HP.PD Release Notes and Readme File	No installation is required to use the platform. The platform is a web-based application and can be accessed via a browser. The deployment of the platform is described in: • Deployment Plan; • Release Notes; • Readme File.
Maintenance and Servicing Information	Healthcare provider	AS.HP.PP.08 Software Maintenance Plan	Software Maintenance Plan
Benefit-risk analysis and risk management			
Risk Management File	Healthcare provider	AS.HP.PP.10 Product Risk Management Plan AS.HP.PD.14 Product Risk Management Plan AS.HP.PD.08 IT Security Risk Assessment	• Risk Management Plan; • Risk Management File; • IT Security Risk Assessment.
Benefit-Risk Analysis	N/A	N/A	No residual risks

Content of the Medical Device File (MDF)

Verification and validation data			
Verification Evidence	Healthcare provider	AS.HP.PP.05 Test Plan AS.HP.PP.06 Test Cases AS.HP.PR.05 Test Report	• Test plans; • Test cases; • Test result reports.
Validation Evidence	Healthcare provider	AS.HP.PP.04 Validation Plan AS.HP.PR.04 Validation Report	• Validation Plan; • Validation Report.
Usability engineering			
Usability Engineering File	Healthcare provider	AS.HP.PD.11 Usability Engineering File	Usability Engineering File
Results of Formative Evaluation	Healthcare provider	AS.HP.PD.11 Usability Engineering File AS.HP.PR.04 Validation Report	Formative evaluation has been performed in the frame of manual testing; the results are reflected in the Validation Report.
Results of Summative Evaluation	N/A	N/A	All hazard-related use errors in the platform's functionality are mitigated.

Content of the Design and Development File (DDF)

Document name	Reference	Comments
DDF	AS.HP.PP.02 Project Management Plan AS.HP.PP.01 Document Management Plan AS.HP.PP Software Development	HA design and development plan is reflected in the following documents: • Project Management Plan; • Document Management Plan; • Software Development Plan.
Design Input Documents	AS.HP.PD.02 Vision and Scope AS.HP.PD.03 Business Requirements Document AS.HP.PD.04 Software Requirements Specification	Design inputs are listed in: • Vision and Scope; • Business Requirements Document; • Software Requirements Specification.
Design Output Documents	AS.HP.PD.05 Software Architecture Document AS.HP.PD.06 Software Design Document AS.HP.PD.01 Traceability Analysis	Design outputs are listed in: • Software Architecture Document; • Software Design Document; • Traceability Analysis.
Design Review Documents	AS.HP.PR.01 Software Specifications Review AS.HP.PR.07 Regulatory Compliance Review AS.HP.PR Medical File Review Report	• AS.HP.PR.01 Software Specifications Review; • AS.HP.PR.07 Regulatory Compliance Review; • AS.HP.PR Medical File Review Report.
Design Verification Evidence	AS.HP.PP.05 Test Plan AS.HP.PP.06 Test Cases AS.HP.PR.05 Test Report	• Test plans; • Test cases; • Test result reports.
Design Validation Evidence	AS.HP.PP.04 Validation Plan AS.HP.PR.04 Validation Report	• Validation Plan; • Validation Report.
Design Transfer Documents	AS.HP.PP.08 Software Maintenance Plan AS.HP.PP.11 Deployment Plan AS.HP.PD.07 Release Notes	• Software Maintenance Plan; • Deployment Plan; • Release Notes.

Content of the Design and Development File (DDF)

Design Change Documents	AS.HP.PP.07 Configuration and Change Management Plan Change Request Log AS.HP.PD.09 Change Request Form	• Configuration and Change Management Plan; • Change Request Log; • Change Request Form.
Product Development Processes and Procedures	Andersen	Andersen's processes, procedures, and templates applied during the design and development: • AS.QMS.P.03 Project Management; • AS.QMS.P.01 Software Development; • AS.QMS.DP.7.3.3 Software Requirements Definition; • AS.QMS.DP.7.3.5 Software Expert Review; • AS.QMS.DP.7.3.6 Usability Engineering; • AS.QMS.DP.7.3.8 Design and Development Transfer; • AS.QMS.DP.7.3.9 Control of Design and Development Changes.