IEC 62366-1:2015 Mapping of Requirements to Documents

This table maps all requirements of the IEC 62366-1:2015 (by section) to the relevant documents.

> 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.

Section	Title	Fulfilled in Document
4.1.1	Usability Engineering Process	SOP Integrated Software Development
4.1.2	Risk Control as it relates to User Interface design	Risk Table
4.1.3	Information for Safety as it relates to Usability	Usability Evaluation Report
4.2	Usability Engineering File	Usability Evaluation Plan, Report
4.3	Tailoring of the Usability Engineering effort	Usability Evaluation Plan
5.1	Prepare Use Specification	SOP Integrated Software Development
5.2	Identify User Interface characteristics related to Safety and potential Use Errors	Software Requirements List
5.3	Identify known or foreseeable Hazards and Hazardous Situations	Risk Table
5.4	Identify and describe Hazard-Related Use Scenarios	List of Hazard-Related Use Scenarios
5.5	Select the Hazard-Related Use Scenarios for Summative Evaluation	List of Hazard-Related Use Scenarios
5.6	Establish User Interface Specification	Software Requirements List
5.7.1	Establish User Interface Evaluation Plan / General	Usability Evaluation Plan
5.7.2	Formative Evaluation planning	Usability Evaluation Plan
5.7.3	Summative Evaluation planning	Usability Evaluation Plan

Section	Title	Fulfilled in Document
5.8	Perform User Interface design, implementation and Formative Evaluation	SOP Integrated Software Development
5.9	Perform Summative Evaluation of the Usability of the User Interface	Usability Evaluation Protocol
5.10	User Interface of Unknown Provenance	(not applicable)