Software Requirements Specification

FDA Unit Test Example – Mobile App

# Purpose

## This document describes the Software Requirements Specifications for the mobile app of the FDA Unit Test Example

# Scope

## This document applies to the FDA Unit Test Example product

# Background

## A Software Requirements Specification (SRS) is a comprehensive, structured document that precisely defines the functional and performance requirements for software used within a medical device or related system. Per FDA Software Guidance, the SRS serves as the pivotal reference for both the development and verification of software, ensuring traceability from system-level requirements down to detailed software functions.

## The SRS articulates what the software must do, encompassing all anticipated behaviors, user interactions, and responses to abnormal or error conditions. It clearly delineates software interfaces, constraints, and any applicable regulatory or safety considerations. By establishing unambiguous criteria for design, implementation, and testing, the SRS minimizes ambiguity, supports risk management, and provides a foundation for consistent quality throughout the software lifecycle. This documentation is essential for demonstrating compliance with regulatory expectations and facilitating effective communication among engineering, quality, and regulatory teams.

## The FDA Unit Test Example provides an example of how the software requirements and verification protocols for a software as a medical device product can be automatically generated from unit tests.

# Responsibilities

## Engineering is responsible for maintaining this document.

# Hardware Requirements

## For iOS devices, the mobile app of the FDA Unit Test Example requires the minimum hardware requirements (processor speed, memory, etc.) of the lowest supported iOS version (iOS 14 at the time of this writing)

# Programming Language Requirements

## The backend of the FDA Unit Test Example shall be written in Swift