

# Docs-as-Code for Open-Source Medical Hardware & PPE's

## Table of Contents

Stakeholder Needs ..... 2

    1: Quality System Processes for Medical Device Manufacturers ..... 2

Data Structures ..... 2

## Stakeholder Needs

The **Docs-as-Code for Open-Source Medical Hardware & PPE's** architecture is guided by a series of stakeholder needs, listed below.

### 1: Quality System Processes for Medical Device Manufacturers

Manufacturers of medical devices shall ensure that finished devices will be safe and effective.<sup>[1][2]</sup>

## Data Structures

This section covers each data structure type in the **Docs-as-Code for Open-Source Medical Hardware & PPE's** architecture.

[1] 21 CFR Part 820 — Quality System Regulation <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820>

[2] ISO 13485 - Quality Management for Medical Devices <https://www.iso.org/iso-13485-medical-devices.html>