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

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Stakeholder Needs

The Docs-as-Code for Open-Source Medical Hardware & PPE's 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.[1][2]

Data Structures

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

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

[2] ISO 18485 - Quality Management for Medical Devices https://www.iso.org/iso-13485-medical-devices.html