ChromaScan Health Standards

- **IEC 60601**
  Standard will be used for testing electrical safety, specifically leakage current testing (10uA).
  Reference Link:
  > [Link 1](#)
  > [Link 2](#)

- **21 CFR 892 - FDA**
  Medical Device Data System MDDS - the device should not modify or control data, just output the patient's past results.
  Reference Link:
  > [Link 3](#)

- **ISO 17664**
  - ISO 17664:2004(E) - Sterilization of Medical Devices -- Information to Be Provided by the Manufacturer for the Processing of Resterilizable Medical Devices.
  - FDA recommends thorough cleaning and low-level disinfection.
  Reference Link:
  > [Link 4](#)

- **IEC 62304**
  Standard will be used to outline the software life cycle processes necessary to ensure the safety and effectiveness of the software
  > i. Ensure compatibility with the test strip interface, data processing, and digital results presentation
  Reference Link:
  > [Link 5](#)

- **ISO 45001**:

  Focuses on occupational health and safety, and includes guidelines for handling chemicals, ensuring worker safety. As part of our testing procedure, this will be needed when testing the color strips with chemicals.
  Reference Link:

  > [Link 6](#)

- **IEC 62133**
  This safety standard defines the requirement and tests for alkaline and other non-electrolytes batteries used in portable medical devices.
  Reference Link:
  > [Link 7](#)