

Applicable Standards

There are many applicable standards to the SonoHand, but the key ones to apply are ones from ASME and ISO. From ASME, SonoHand has to meet drawings standards, such as ASME Y14.100-2017. This standard establishes the essential requirements and reference documents applicable to the preparation and revision of manual or computer generated engineering drawings and associated lists unless tailored by a specialty standard. In the US, this is a general standard that has to be met for a drawing to be considered acceptable and distributable. From ISO, SonoHand has to meet ISO 13485, the specific standard for medical devices. ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. A number of regulatory authorities have adopted the ISO 13485 certification standard as part of their own requirements to enable the sale of medical devices on their territory. If SonoHand wants to be mass produced, then it has to meet the specific terms stated within this standard.