ISO Standards Applied to Medical Device Manufacturing

What is ISO?
ISO is a worldwide organization that promotes proprietary, industrial and commercial standards in 164 countries. The headquarters are located in Geneva, Switzerland where voluntary organization members are recognized as authorities on standards, and each participating country has one representative. They hold annual meetings to discuss various ISO strategies, objectives and other important certifications.

ISO 13485
This specific certification standard was published in 2003 and represents the requirements for a comprehensive quality management system that is used for the design and manufacture of medical devices. Companies certified as ISO 13485 compliant manufacture medical devices that meet high quality standards that are consistently maintained and their quality control system is effectively implemented.

ISO 9001:2008
When it comes to designing and developing products, holding the ISO 9001:2008 certificate sets precedence because it signifies that a company engages in the creation of new products. Additionally, it requires that the development of manufactured products have an approval process and a set of rigorous quality standards and development records before the product is distributed. This gives an extra measure of excellence to ensure manufactured materials are superior.