



iSirona: Integrating Quality into Everything We Do

QUALITY POLICY

Every member of the iSirona team is committed to the development, installation and distribution of reliable products that are in accordance with industry, customer and regulatory requirements. This commitment is put into action through our insistence on continuous improvement, team accountability and, most importantly, the complete satisfaction of our customers.

REGULATORY POSITION

Hospitals that implement our solution can be assured that iSirona's products and systems are developed in accordance with the necessary Quality System Regulation (QSR) controls as set forth by the FDA. These controls (which define and provide an acceptable level of assurance for products distributed to the domestic market) guide our efforts through the entire product life cycle. And, our approach is in direct alignment with the proposed position of the FDA related to medical device data systems manufacturers.

THE FDA'S CURRENT POSITION

In February of 2008, the FDA proposed the reclassification of medical device data systems (MDDS), stating they should become Class I medical devices that are developed in accordance with the Quality System Regulation requirements and be exempt from 510K pre-market approval. The FDA's position is stated as follows:

"The FDA has recognized that the Class III requirements are not necessary for ensuring the safety and effectiveness of MDDS devices and has been exercising enforcement discretion with MDDS device manufacturers. These firms have not been required to submit PMAs or meet the requirements typically required for manufacturers of CLASS III devices, but the agency believes that all or nearly all firms in this industry have in place good business practices, including quality systems. If the FDA were to discontinue enforcement discretion, most firms would continue to comply with Class I provisions."



For more information about iSirona's products and the company's commitment to quality, please contact iSirona at 866-202-2124 or visit us at www.isirona.com.