

## **STERIS Isomedix Services Quality Manual Summary**



The Quality Manual documents STERIS Isomedix Services' Quality Management System in order to demonstrate the company's ability to consistently provide sterilization processing services that meet customer and regulatory requirements. This manual establishes compliance with those standards and regulations listed in the normative references section of this manual.

The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide a general description of all processes comprising the quality system. This manual is also used to present the quality system to customers, suppliers, regulators and other external interested parties, and to inform them of the specific controls that are implemented at STERIS Isomedix Services to assure quality. This Quality Manual does not create any legal or regulatory obligation or standard of performance beyond that specifically required of STERIS Isomedix Services and STERIS Corporation by current, applicable statutory or regulatory law.

To provide consistent quality service to our customers, the Quality Manual extends over all 21 facilities belonging to the STERIS Isomedix Services business unit. Quality system level-2 procedures are standardized and, in addition, procedures that control the technological processes and work instructions are aligned within each technology – Gamma, Electron beam, and Ethylene Oxide. These procedures are listed in the appendix to the Quality Manual.

The Quality Manual follows the format of ISO 13485:2003 standard. It also establishes compliance with FDA QSR. Compliance with the STERIS Corporation Quality Manual is established by citing that manual as a top-level document. The Quality Manual describes in table format, the levels of the STERIS Isomedix documentation system and the primary documents contained in each level.

STERIS Isomedix Services does not provide design and development services and does not clean, install or service devices, and does not manufacture implantable medical devices. Therefore, appropriate exclusions have been taken to ISO 13485:2003 and 21CFR part 820 and are listed in the Quality Manual.