4.1 General requirements

Your company has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 13485:2003 and ISO 9001:2000. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS *Your Company* has:

- Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, *and documented them in quality plans, work instructions and the Measuring, Monitoring and Analysis Table*
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- Established systems to monitor, measure and analyze these processes, and
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- A documented Quality Policy
- This Quality Manual
- Documented Procedures
- Documents identified as needed for the effective planning, operation and control of our processes, and
- Quality Records
- Any other documentation specified by national or regional regulations.
- Each procedure, activity or special arrangement that has been documented is also implemented and maintained.
- For each type or model of medical device, a file is maintained containing or identifying documents defining product specifications and quality management system requirements.
- These documents define the complete manufacturing process and, if applicable, installation and servicing.