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# ISO 13485:2003 ISO 9001:2000 Quality Systems Manual

Street Address  
City, State Zip

\*This manual is to be used as a template in developing your 13485 Quality Manual. Review the text; replace text to match your quality system requirements. At a minimum, the blue text should be replaced with your information. This Quality Manual is designed to accommodate both ISO 9001 & ISO 13485, but if you only want ISO13485—please delete highlighted items.

### Introduction

*Your Company* developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of *Your Company* meets the requirements of the international standard **ISO 13485:2003** and ISO **9001:2000**. This system addresses the design, development, production, installation, and servicing of the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of **ISO 13485:2003** and **ISO 9001:2000**. Each section begins with a policy statement expressing *Your Company's* obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements. **Note: ISO 13485 has not been updated to ISO 9001:2008 yet.**

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

President: \_\_\_\_\_

**NOTES: DELETE AFTER EACH TASK IS COMPLETED.**

- **USE REPLACE FUNCTION – ENTER “ YOUR COMPANY ” IN FIND SPACE, ENTER YOUR COMPANY NAME IN REPLACE SPACE – SYSTEM SHOULD MAKE CHANGES THROUGHOUT THE ENTIRE DOCUMENT.**
- **(IF ANY OTHER INFORMATION IS AVAILABLE, THAT WOULD FURTHER ENHANCE THE COMPANY INTRODUCTION, PREFERABLY ELECTRONICALLY,**

## Section 1: Scope

### 1.1 General

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Describe the scope of your QMS:

The quality manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the International Standard ISO 13485:2003 and the **ISO 9001:2000**

### 1.2 Application

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**Your Company** has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

- Identify permissible exclusions. If none, document that there are no exclusions. Document the justification for any exclusions that are made.

## 4.1 General requirements

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*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

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### 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.



# Section 7

# Product Realization