

QUALITY MANUAL

TEMPLATE PART 1



DeviceHQ

DeviceHQ Quality Manual Part 1

1.0 General

The purpose of this document is to define the quality management system for the manufacture of medical devices. The system is designed to ensure that all products are manufactured to the required quality standards, and to maintain a high level of customer satisfaction.

2.0 Scope

This document applies to the design, development, manufacture, and distribution of medical devices.

3.0 Responsibilities

3.1 General

- 3.1.1 The Quality Manager is responsible for the overall quality management system.
- 3.1.2 The Technical Manager is responsible for the design and development of medical devices.
- 3.1.3 The Manufacturing Manager is responsible for the manufacture of medical devices.
- 3.1.4 The Quality Control Manager is responsible for the quality control of medical devices.
- 3.1.5 The Sales Manager is responsible for the distribution of medical devices.

3.2 Design

- 3.2.1 The Technical Manager is responsible for the design of medical devices.
- 3.2.2 The Quality Control Manager is responsible for the review and approval of design documents.

3.3 Manufacturing

- 3.3.1 The Manufacturing Manager is responsible for the manufacture of medical devices.
- 3.3.2 The Quality Control Manager is responsible for the quality control of manufactured medical devices.

3.4 Quality Control

- 3.4.1 The Quality Control Manager is responsible for the quality control of medical devices.
- 3.4.2 The Quality Control Manager is responsible for the review and approval of manufacturing documents.

3.5 Sales

- 3.5.1 The Sales Manager is responsible for the distribution of medical devices.

3.6 Other

- 3.6.1 The Quality Manager is responsible for the overall quality management system.
- 3.6.2 The Technical Manager is responsible for the design and development of medical devices.
- 3.6.3 The Manufacturing Manager is responsible for the manufacture of medical devices.
- 3.6.4 The Quality Control Manager is responsible for the quality control of medical devices.
- 3.6.5 The Sales Manager is responsible for the distribution of medical devices.

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