

# **Reliable Design of Medical Devices – 3th. ed**

ISBN 9781439894910

## **Table of contents**

### **The Basics of Reliability**

Reliability

The Concept of Failure

The Product Design and Development Process

### **The Concept Phase**

Defining the Device

Safety and Risk Management

Documents and Deliverables

### **The Feasibility Phase**

The FDA

The Medical Devices Directives

Important Medical Device Standards

Human Factors

Requirements Engineering

Liability

Intellectual Property

The Project Team

The Reliability Goal and Plan

Documents and Deliverables

### **The Design Phase**

Hardware Design

Hardware Risk Analysis

Design and Project Metrics

Design for Six Sigma

Software Design

Software Coding

Software Risk Analysis

Software Metrics

Documents and Deliverables

### **Verification and Validation**

The Basis and Types of Testing

Hardware Verification and Validation

Hardware Data Analysis

Software Verification and Validation

Software Data Analysis

Documents and Deliverables

### **Design Transfer and Manufacturing**

Transfer to Manufacturing

Hardware Manufacturing

Software Manufacturing

Configuration Management  
Documents and Deliverables

**Field Activity**

Analysis of Field Data  
Monitored Activity

**Appendices**

**Index**