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<b>Issued by: Quality Assurance</b>	<b>Effective Date: 6/6/2011</b>	<b>Rev. A</b>	<b>Pg. 1 of 5</b>
Approved: 6/6/2011 5:48 PM - Alan Halko, Quality Manager			

*Organization of this manual is the same as the sectional organization of ISO 13485:2003. Close correspondence between the manual and the standard helps to demonstrate compliance of the system and ensures that all clauses and requirements have been addressed systematically.*

*Note that each section of the manual is an independent document with its own page numbering, approval and release signatures, and revision level.*

*You have probably noted that some sections have titles that are not exactly the same as in the standard. The changes are intentional, to better describe the content of the section, or to use a more established and traditional terminology.*

## QUALITY SYSTEM MANUAL

### SECTION 0 - INDEX AND REVISION STATUS

### SECTION 1 - SCOPE

- 1.1 Quality Policy
- 1.2 Introduction
- 1.3 Application
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### SECTION 3 - TERMS AND DEFINITIONS

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SECTION 7 - PRODUCT REALIZATION

- 7.1 Planning of Product Realization
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- 7.3 Design Control
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SECTION 8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

- 8.1 Planning of Monitoring and Measurement
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- 8.3 Control of Nonconforming Product
- 8.4 Analysis of Data
- 8.5 Continual Improvement

**QUALITY SYSTEM OPERATIONAL PROCEDURES**

*Instructions in 'Procedures' folders explain which procedures are mandatory and which are optional. After you remove a procedure from the system make sure to coordinate pertinent references in the Quality Manual and in other operational procedures.*

- QOP-42-01 Control of Documents
- QOP-42-02 Device Master Record
- QOP-42-03 Control of Records
- QOP-56-01 Management Review
- QOP-62-01 Competence, Awareness and Training
- QOP-63-01 Equipment Maintenance



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- QOP-64-01 Production and Work Environment
- QOP-71-01 Production Planning
- QOP-71-02 Process Risk Management
- QOP-72-01 Order Processing and Review
- QOP-73-01 Design Control
- QOP-73-02 Design Risk Management
- QOP-73-03 Control of Design and Process Changes
- QOP-74-01 Supplier Evaluation and Monitoring
- QOP-74-02 Purchasing
- QOP-74-03 Verification of Purchased Product
- QOP-75-01 Production Work Order and History Record
- QOP-75-02 Cleanliness and Contamination of Product
- QOP-75-03 Validation of Processes and Software
- QOP-75-04 Installation and Servicing
- QOP-75-05 Product Identification and Traceability
- QOP-75-06 Labeling and Packaging
- QOP-75-07 Storage and Distribution
- QOP-76-01 Measuring and Monitoring Equipment
- QOP-82-01 Feedback and Customer Satisfaction
- QOP-82-02 Internal Quality Audits
- QOP-82-03 In-process Inspections
- QOP-82-04 Final Acceptance Inspection
- QOP-83-01 Control of Nonconforming Product
- QOP-84-01 Analysis of Data
- QOP-85-01 Continual Improvement
- QOP-85-02 Device Recall and Advisory Notices
- QOP-85-03 Customer Complaints

QOP-85-04 Corrective and Preventive Action

**MANUAL RECORDS/FORMS**  
*(these are printable, manual forms)*

QF-42-02-1 Device Master Record Index  
QF-73-01-1 Design Project Plan and Schedule  
QF-73-01-2 Design Review Report  
QF-73-02-1 Design Risk Analysis  
QF-73-03-3 Engineering Change Notice (ECN)  
QF-75-01-1 Production Work Order  
QF-75-04-1 Service Report  
QF-82-02-1 Internal Audit Checklist

**ELECTRONIC ISOXpress RECORDS/FORMS**  
*(these forms are data entry windows in ISOXpress software)*

ER-42-01-1 Document Control Record (ISOXpress system)  
ER-56-01-1 Management Review Report (ISOXpress system)  
ER-56-01-2 Quality Objectives Record (ISOXpress system)  
ER-62-01-1 Training Program Record (ISOXpress system)  
ER-62-01-2 Personnel Training Record (ISOXpress system)  
ER-62-01-3 Competency Certification Program Record (ISOXpress system)  
ER-62-01-4 Personnel Competency Certification Record (ISOXpress system)  
ER-74-01-1 Approved Supplier List (ISOXpress system)  
ER-74-01-2 Supplier Nonconforming Product Records (ISOXpress system)  
ER-74-01-3 Supplier Corrective Action Requests (ISOXpress system)  
ER-76-01-1 Measuring Device Records (ISOXpress system)  
ER-82-02-1 Internal Audit Plan (ISOXpress system)  
ER-82-02-2 Internal Audit Report (ISOXpress system)



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- ER-82-02-3 Internal Audit Finding Report (ISOXpress system)
- ER-83-01-1 Product Nonconformity Report (ISOXpress system)
- ER-85-02-1 Customer Complaint Reports (ISOXpress system)
- ER-85-03-1 Corrective/Preventive Action Records (ISOXpress system)