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Approved: 8/31/2017 12:35 PM - Allan Halko, Quality Assurance Manager			

Organization of this manual is the same as the sectional organization of ISO 13485:2016. 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 MANAGEMENT SYSTEM MANUAL

SECTION 0 - INDEX AND REVISION STATUS

SECTION 1 - SCOPE

1.1 Quality Policy

1.2 Introduction

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SECTION 2 - REFERENCE DOCUMENTS

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4.1 Quality System Processes

4.2 Documentation and Records

SECTION 5 - MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

5.2 Customer Focus

5.3 Quality Policy

5.4 Quality System Planning

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SECTION 6 - RESOURCE MANAGEMENT

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- 6.2 Competence, Awareness and Training
- 6.3 Infrastructure
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SECTION 7 - PRODUCT REALIZATION

- 7.1 Planning of Product Realization
- 7.2 Customer-related Processes
- 7.3 Design Control
- 7.4 Purchasing
- 7.5 Production
- 7.6 Monitoring and Measuring Equipment

SECTION 8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

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

QMS OPERATIONAL PROCEDURES AND FORMS

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-xx-xx are Quality Operational procedures

QOP-xx-xx-Fx are traditional, manual (MS Word files) forms that you must open in Word or print out to fill them out.

EF-xxx-x are electronic data entry forms in the IMSXpress software. These are the windows with data entry fields (text boxes, drop-downs, date pickers, etc.) that you open when you want to create a new record or open an existing record.

- QOP-41-01 Risk Management
 - EF-380-1: Risk Project
 - EF-380-2: Risk Case



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- QOP-41-02 Risk Reduction Actions and Controls
EF-380-3: Risk Reduction Action
- QOP-41-03 Validation of Software
QOP-41-03-F1 Software Validation Plan/Report
QOP-41-03-F2: Software Validation Test Case
- QOP-42-01 Control of Documents
EF-120-1: New Document
EF-120-2: Document Revision Record
- QOP-42-02 Control of Document Changes
EF-390-1 Change Request
- QOP-42-03 Control of Records
- QOP-42-04 Device Master Record
QOP-42-04-F1: Device Master Record Index
- QOP-56-01 Management Review
EF-150-01: QMS Management Review
EF-150-02: Review Items
EF-150-03: Quality Objective
- QOP-62-01 Competence, Awareness and Training
EF-160-1: Document Training Program
EF-160-2: General Training Program
EF-160-3: Job/Position
EF-160-4: Job/Position Certification
EF-160-5: Personnel Record
- QOP-62-02 Work Instructions and Training
- QOP-63-01 Equipment Maintenance
EF-270-1: Equipment
EF-270-2: Maintenance Program
EF-270-3: Maintenance Work Order
EF-270-4: Maintenance Part
- QOP-64-01 Production and Work Environment
- QOP-71-01 Design Transfer and Production Planning
- QOP-71-02 Process Risk Management
EF-380-1: Risk Project
EF-380-2: Risk Case
EF-380-3: Risk Reduction Action
- QOP-72-01 Order Processing and Review



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- QOP-73-01 Design Control
QOP-73-01-F1: Design Project Plan and Schedule
- QOP-73-02 Design Risk Management
EF-380-1: Risk Project
EF-380-2: Risk Case
EF-380-3: Risk Reduction Action
- QOP-73-03 Control of Design Changes
EF-390-1 Change Request
- QOP-74-01 Supplier Evaluation and Monitoring
EF-180-1: Supplier
EF-180-2: Nonconforming Delivery
EF-180-3: Corrective Action Request
- QOP-74-02 Purchasing
- QOP-74-03 Verification of Purchased Product
- QOP-75-01 Production Work Order and History Record
QOP-75-01-F1: Production Work Order
- QOP-75-02 Cleanliness and Contamination of Product
- QOP-75-03 Validation of Processes
- QOP-75-04 Control of Process Changes
EF-390-1 Change Request
- QOP-75-05 Installation and Servicing
QOP-75-05-F1 Service Report
- QOP-75-06 Product Identification and Traceability
- QOP-75-07 Labeling and Packaging
- QOP-75-08 Storage and Distribution
- QOP-76-01 Measuring and Monitoring Equipment
EF-200-1: Measuring Equipment
- QOP-82-01 Feedback and Customer Satisfaction
- QOP-82-02 Internal Quality Audits
QOP-82-02-F1: Internal Audit Checklist
EF-140-1: Quality System Audit
EF-140-2: Audit Plan Item
EF-140-3: Audit Finding
- QOP-82-03 In-process Inspections



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- QOP-82-04 Final Inspection and Product Release
- QOP-83-01 Control of Nonconforming Product
EF-170-1: Nonconforming Product
- QOP-84-01 Analysis of Data
- QOP-85-01 Device Recall and Advisory Notices
- QOP-85-02 Complaints
EF-190-1: Complaint
- QOP-85-03 Corrective and Preventive Action
EF-130-1: Corrective Action