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| **Auditor** | **Areas of the QMS to be Audited**  **(Reg Requirement)** | **QMS Document** | **Completed By/Date** |
|  | ISO 13485:2016 (Requirement Clause) |  |  |
|  | **Management Subsystem**   * Quality Management System/ Quality Manual/ Quality Policy *(4.1/4.2/5.3)* * Organizational Roles (4.1.1) * Quality planning *(5.4)* * Customer Focus/ Customer Satisfaction *(5.2)* * Management Commitment/ Responsibility/ Authority/ Internal Communication *(5.1/5.5)* * Provision of resources *(6.1/6.2)* * Management review/ Analysis of Data *(5.6/8.4)* | Quality Manual  QP-0013 |  |
|  | **Documentation and Records Subsystem**   * Approval of documents and changes (4.2.4) * Control of documents of external origin (4.2.4) * Device Master Records (4.2.3) * Approval of labelling incl. translation process (4.2.4) * Document distribution and linkage to the training process (4.2.4) * Document and Records retention (4.2.1/ 4.2.5) | QP-0003  QP-0003  QP-0003  QP-0003  QP-0003  QP-0018 |  |
|  | **Human Resources**   * Competence evaluation and training (6.2) * Records of education, training, skills and experience (4.2.5) * Quality System, MDD (6.2) | QP-0004  QP-0004  QP-0004 |  |
|  | **Risk Management**   * Risk Management (7.1/ MDD) | QP-0017 |  |
|  | **Purchasing Controls Subsystem**   * Supplier evaluation and selection (7.4.1) * Supplier controls and monitoring (7.4.1) * Verification of purchased products- process (7.4.3) * Specifications (adequacy) for products and services (7.4.2) | QP-0023  QP-0023  QP-0005  QP-0005 |  |

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|  | **Design and Development Subsystem**   * Design and Development Planning (7.3.2) * Design and Development Inputs (7.3.3) * Design and Development Outputs (7.3.4) * Design and Development Review (7.3.5) * Design and Development Verification (7.3.6) * Design and Development Validation (7.3.7) * Design and Development Transfer (7.3.8) * Control of Design and Development Changes (7.3.9) * Design and Development Files (7.3.10) | QP-0002  QP-0002  QP-0002  QP-0002  QP-0002  QP-0002  QP-0002  QP-0002  QP-0002 |  |
|  | **Production & Process Controls Subsystem**   * Process to control nonconforming products (8.3) * MRB- review, investigation and disposition of nonconforming products (8.3/8.5.2). * Nonconforming products in distribution- internal company vs. customer controlled (8.3/8.5.2) * Receiving Inspection (7.4.3, 8.3) * Requirements for products and materials * Acceptance activities, status and records * Handling of materials (6.3, 7.5.11) * Warehousing (6.3/ 6.4) * Control of production (7.5.1) * Product/ material identification and traceability (7.5.8) * Process control and monitoring (7.5) * monitoring and control of process parameters (8.2.5) * approval of processes and process equipment (7.5.6): * Handling of products (7.5.11) * In-process and finished device testing/acceptance status (7.5.8/ 8.2.6) * Labeling and packaging operations (7.5.1) * Device History Records- review (4.2.4) * Handling of customer property (7.5.10) * Calibration System- monitoring and measuring equipment (7.6) * Preventive Maintenance program (6.3) * Equipment qualification/ validation and process validation incl. software validation (7.5.6) | QP-0008  QP-0008  QP-0008  QP-0005  QP-0016  QP-0022  Ops WI  QP-0007  QP-0013  QP-0016  Ops Docs  QP-0006  QP-0007  QP-0019  QP-0014  QP-0014  QP-0026 |  |

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|  | **Outsourcing / Planning of Product Realization**   * Identification and control of Outsourced processes (4.1/ 7.4.1) * Notification of changes to Notified Body/ Health Canada (4.1, 7.2.1/ 7.3.7) | QP-0023  QP-0028/  QP-0029 |  |
|  | **Customer Related Processes**   * Contract Review (7.2.1/7.2.2/7.2.3) | Ops WI |  |
|  | **CAPA Subsystem**   * Experience from post-production phase/ Customer communication/ Feedback (7.2.3/8.2.1) * CAPA- corrective/ preventive actions, Distribution of Nonconforming Products (8.3/8.5.1-3) * EU Vigilance System incl. Advisory Notices (8.5.1) * Health Canada Mandatory Problem Reporting/ Recall (8.5.1) * Analysis of data- Monitoring & Measurement of Processes/ Statistical Techniques (8.4/8.2.3) | QP-0011  QP-0012  QP-0011  QP-0021  QP-0013 |  |
|  | **Internal Audits & Improvement**   * Audit program incl. ISO 13485, CMDR, MDD, other requirements (8.2.4) * Process, documentation, linkage to CAPA (8.2.2/8.5.2) | QP-0015  QP-0015 |  |
|  | **MDD Medical Device Directive** |  |  |
|  | **MDD Medical Device Directive**   * EU Authorized Representative * Essential Requirements (Article 3, Annex I) * Information supplied by manufacturer (Annex I Sec 13; Article 17) * Information and notification of post-production incidents (Article 10; Annex II; 3.1) * Clinical Evaluation and Post Market Surveillance (Annex X; Article 15) | QP-0028  QP-0002  QP-0006  QP-0011/ QP-0024  QP-0024/ QP-0027 |  |
|  | **Canadian Medical Device Regulations** |  |  |
|  | **Canadian Medical Device Regulations**   * Review of Canadian Device Licenses/ Amendments * Safety and Effectiveness Requirements * Labeling Requirements | QP-0029  QP-0002  QP-0006 |  |
|  | **US FDA Regulations** |  |  |
|  | **Part 11 – Electronic Records; Electronic Signatures**   * General Provisions * Electronic Records * Electronic Signatures | Ops Docs |  |
|  | **Part 801 – Labeling**   * General Labeling Provisions * Labeling Requirements for Unique Device Identification * Labeling Requirements for Over-the-Counter Devices * Exemptions from Adequate Directions for Use * Special Requirements for Specific Devices | QP-0006  QP-0006  QP-0006  QP-0006  QP-0006 |  |
|  | **Part 803 – Medical Device Reporting**   * General Provisions * Generally Applicable Requirements for Individual Adverse Event Reports * User Facility Reporting Requirements * Manufacturer Reporting Requirements | QP-0021 |  |
|  | **Part 806 – Medical Devices; Reports of Corrections and Removals**   * General Provisions * Reports and Records | QP-0021 |  |
|  | **Part 830 – Unique Device Identification**   * Requirement for a Unique Device Identifier * FDA Accreditation of an Issuing Agency * FDA as an Issuing Agency * Global Unique Device Identification Database | QP-0025 |  |