ISO CERTICATION

ISO 14001:

Mandatory documents and records required by ISO 14001:

Here are the documents you need to produce if you want to be compliant with ISO 14001:

- Scope of the EMS (clause 4.3)
- Environmental policy (clause 5.2)
- Risk and opportunities to be addressed and processes needed (clause 6.1.1)
- Criteria for evaluation of significant environmental aspects (clause 6.1.2)
- Environmental aspects with associated environmental impacts (clause 6.1.2)
- Significant environmental aspects (clause 6.1.2)
- Environmental objectives and plans for achieving them (clause 6.2)
- Operational control (clause 8.1)
- Emergency preparedness and response (clause 8.2)

Mandatory records:

- Compliance obligations record (clause 6.1.3)
- Records of training, skills, experience and qualifications (clause 7.2)
- Evidence of communication (clause 7.4)
- Monitoring and measurement results (clause 9.1.1)
- Internal audit program (clause 9.2)
- Results of internal audits (clause 9.2)
- Results of the management review (clause 9.3)
- Results of corrective actions (clause 10.1)

ISO 27001:

Mandatory documents and records required by ISO 27001:

- Scope (4.3)
- Information security policy (5.2 e)
- Information security risk assessment process (6.1.2)
- Information security risk treatment process (6.1.3)
- Statement of Applicability (6.1.3)
- Information security objectives (6.2)
- Evidence of competence (7.2)
- That “determined by the organization as being necessary for the effectiveness of the ISMS” (7.5.1 b)
- The extent necessary to have confidence that the processes required for operational planning and control have been carried out as planned (8.1)
- Results of information security risk assessments (8.2)
- Results of information security risk treatment (8.3)
- Evidence of the information security performance monitoring and measuring results (9.1)
- Internal audit programme(s) and the audit results (9.2 g)
- Internal audit procedure (ISO 27000:2014, sec. 2.5)
- Evidence of the results of management reviews (9.3)
- Evidence of the nature of the nonconformities and any subsequent actions taken, and the results of any corrective actions (10.1)

ISO 13485:

Mandatory documents and records required by ISO 13485:

- Roles undertaken by the organization under applicable regulatory requirements (clause 4.1.1)
- Procedure and records for the validation of the application of computer software (clause 4.1.6)
- Quality Manual (clause 4.2.2)
- Medical device file (clause 4.2.3)
- Procedure for document control (clause 4.2.4)
- Procedure for record control (clause 4.2.5)
- Quality policy (clause 5.3)
- Quality objectives (clause 5.4.1)
- Responsibilities and authorities (clause 5.5.1)
- Procedure and records for management review (clause 5.6.1)
- Procedure for training (clause 6.2)
- Requirements for infrastructure and maintenance activities (clause 6.3)
- Requirements for work environment (clause 6.4.1)
- Arrangements for control of contaminated or potentially contaminated product (clause 6.4.2)
- Process for risk management in product realization (clause 7.1)
- Outputs of product realization planning (clause 7.1)
- Records of the results of the customer requirements review and actions arising from it (clause 7.2.2)
- Arrangements for communication with customers (clause 7.2.3)
- Procedure for design and development (clause 7.3.1)
- Design and development planning (clause 7.3.2)
- Design and development outputs (clause 7.3.4)
- Records of design and development review (clause 7.3.5)
- Design verification plans, results and conclusions (clause 7.3.6)
- Design validation plans, results and conclusions (clause 7.3.6)
- Procedure for transfer of design and development outputs to manufacturing (clause 7.3.8)
- Procedure and records for control of design and development changes (clause 7.3.9)
- Design and development file (clause 7.3.10)
- Procedure for purchasing (clause 7.4.1)
- Criteria and records for evaluation and selection of suppliers (clause 7.4.1)

- Record of verification of purchased product (clause 7.4.3)
- Record for each medical device or batch that provides traceability (clause 7.5.1)
- Requirements for cleanliness of product (clause 7.5.2)
- Requirements for medical device installation and acceptance criteria for verification of installation (clause 7.5.3)
- Records for medical device installation and verification of installation (clause 7.5.3)
- Procedure and records for servicing of the medical device (clause 7.5.4)
- Records of sterilization process (clause 7.5.5)
- Procedure and records of production and service provision process validation (clause 7.5.6)
- Procedure and records for validation of process for sterilization and sterile barriers systems (clause 7.5.7)
- Procedure for product identification (clause 7.5.8)
- Procedure for traceability (clause 7.5.9.1)
- Records of traceability and name and address of the shipping package consignee (clause 7.5.9.2)
- Report on changes on customer property (clause 7.5.10)
- Procedure for preserving the conformity of product (clause 7.5.11)
- Procedure for monitoring and measuring (clause 7.6)
- Record of calibration (clause 7.6)
- Procedure and records for validation of the application of computer software used for monitoring and measuring (clause 7.6)
- Procedure for customer feedback (clause 8.2.1)
- Procedure and records for complaint handling (clause 8.2.2)
- Records of reporting to regulatory authorities (clause 8.2.3)
- Procedure for internal audit (clause 8.2.4)
- Records of audits and their results (clause 8.2.4)
- Identity of the person authorizing release of product (clause 8.2.6)
- Procedure and record of control of nonconforming product (clause 8.3.1)
- Records of rework (clause 8.3.4)
- Procedure and records for data analysis (clause 8.4)
- Procedure and records for corrective action (clause 8.5.2)
- Procedure and records for preventive action (clause 8.5.3)

SA8000:

SA8000 Standard Documentation:

- SA8000 Manual as per Social Accountability standard requirements
- SA8000 mandatory procedures
- Occupational, Health, Safety procedures.
- Set of Social Policies written in plain English.
- Templates for Social Committee.
- SA8000 Formats and Templates written in plain English.
- Standard operation procedures.
- SA8000 Audit Checklist - to verify implemented Social environment in organization.