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| **Prepared By** | **Approved By** | **Date** |
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**ISO 13485:2016**

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**List of Documents**

# ISO 13485:2016 Package - Included Documents

This document outlines the comprehensive list of procedures, records, forms, manuals, policies, and SOPs included in the ISO 13485:2016 Package. These resources are designed to ensure compliance with medical device quality management system (QMS) standards and facilitate the implementation of an effective QMS.

## Package Features

- Full lifetime access

- Access on a laptop, desktop, and mobile

- Certificate of completion

## Procedures

|  |  |
| --- | --- |
| No. | Procedure Name |
| 1 | Quality Manual |
| 2 | Document Control Procedure |
| 3 | Record Control Procedure |
| 4 | Management Review Procedure |
| 5 | Internal Audit Procedure |
| 6 | Corrective Action Procedure |
| 7 | Preventive Action Procedure |
| 8 | Risk Management Procedure |
| 9 | Design and Development Procedure |
| 10 | Purchasing Procedure |
| 11 | Supplier Evaluation Procedure |
| 12 | Receiving Inspection Procedure |
| 13 | Production Control Procedure |
| 14 | Calibration Procedure |
| 15 | Maintenance Procedure |
| 16 | Training Procedure |
| 17 | Nonconforming Product Procedure |
| 18 | Complaint Handling Procedure |
| 19 | Advisory Notice Procedure |
| 20 | Regulatory Reporting Procedure |
| 21 | CAPA Procedure |

## Manual and Quality Policy

|  |  |
| --- | --- |
| No. | Document Name |
| 1 | Quality Manual |

## Standard Operating Procedures (SOPs)

|  |  |
| --- | --- |
| No. | SOP Name |
| 1 | SOP for Quality System Maintenance |
| 2 | SOP for Change Management |
| 3 | SOP for Labeling and Packaging |
| 4 | SOP for Product Storage and Distribution |
| 5 | SOP for Traceability |
| 6 | SOP for Validation and Verification Activities |
| 7 | SOP for Installation and Servicing |
| 8 | SOP for Sterilization Process Control (if applicable) |
| 9 | SOP for Cleanroom Procedures (if applicable) |
| 10 | SOP for Software Validation (if applicable) |
| 11 | SOP for Post-Market Surveillance |
| 12 | SOP for Medical Device Reporting |
| 13 | SOP for Cybersecurity Management (if applicable) |
| 14 | SOP for Environmental Monitoring (if applicable) |
| 15 | SOP for Product Return and Recall |