

## ISO 13485-2003 Audit Checklists-and Guide for QMS Medical Devices

**Description:** This Audit Checklist was designed for organizations that are in need for assessing and for auditing Quality Management Systems based on the International Standard ISO 13485-2003 Medical Devices.

The audit checklist addresses all 61 main and sub-clauses and the 328 shall requirements stated in the standard, in form of questions. Under the response column the question is answered in part by referring to respective standard clauses the question pertains to. A simple rating system has been included that enables the user to record compliance measurement based on the audit findings, quickly and easily.

**Contents:**

1. Title Sheet.
2. Introduction.
3. Description on how to apply and use the audit checklists.
4. Short introduction into audit requirements, discerning minor versus major nonconformities, and how to tally respective findings and rate the findings accordingly.
5. Audit Checklist with 385 audit questions addressing each and every shall requirement stated in the standard.
6. Rating Chart.
7. CD ROM, MS Word 7.0, contains all the above outlined documentation including the audit checklist.

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