This template is best implemented in an excel / sheets file. Note that an audit program most commonly covers all ISO 13485 requirements in the course of three years at minimum.

# Audit Program <Company Name> 2023 - 2026

## 1. General Information

| Auditing Interval | 01/2023 - 01/2026 |
| --- | --- |
| Auditing objective: | <e.g. “13485 compliance” or “preparation for MDR conformity assessment” or “supplier surveillance”> |
| Chances and risks: | <for example: chances - “small company, planning to be audited by an external party to avoid blind spots”> |

## 2. Audit Program Plan

| Audit ID | #1 | #2 | #3 | (…) |  |
| --- | --- | --- | --- | --- | --- |
| Date | <dd.mm.2023> | <dd.mm.2024> | <dd.mm.2025> | <dd.mm.2026> |  |
| Lead auditor | (…) | (…) | (…) | (…) |  |
| ISO 13485:2016, para. 4.1, 4.21:General QMS requirements | x |  |  | x |  |
| ISO 13485:2016, para. 4.2.2, 5.3, 5.4:Quality manual and QMS planning | x |  |  | x |  |
| ISO 13485: 2016, para. 4.2.3:Medical device file |  | x | x |  |  |
| ISO 13485:2016, para. 4.2.4, 4.2.5:Control of documents and records | x |  |  | x |  |
| ISO 13485:2016, para. 5.1, 5.2, 5.3., 5.4, 5.5:Management responsibility | x |  |  | x |  |
| ISO 13485:2016, para. 5.6:Management review | x |  |  | x |  |
| ISO 13485:2016, para. 6.1, 6.3:Resource management | x |  |  | x |  |
| ISO 13485:2016, para. 6.2:Human resources management | x |  |  | x |  |
| ISO 13485:2016, para. 6.4:Work environment and contamination control | n/a | n/a | n/a | n/a |  |
| ISO 13485:2016, para. 7.1:Planning product realization |  | x |  |  |  |
| ISO 13485:2016, para. 7.2:Customer-related processes |  |  | x |  |  |
| ISO 13485:2016, para. 7.3:Design and development |  | x |  |  |  |
| ISO 13485:2016, para. 7.4:Purchasing |  | x |  |  |  |
| ISO 13485:2016, para. 7.5:Production and service provision |  | x |  |  |  |
| ISO 13485:2016, para. 7.6:Measuring equipment |  | x |  |  |  |
| ISO 13485:2016, para. 8.1, 8.2.1, 8.2.2:Feedback and complaints handling |  |  | x |  |  |
| ISO 13485:2016, para. 8.1, 8.2.3:Reporting to authorities |  |  | x |  |  |
| ISO 13485:2016, para. 8.1, 8.2.4:Internal auditing |  |  | x |  |  |
| ISO 13485:2016, para. 8.1, 8.2.5, 8.2.6:Measurement of products and processes |  |  | x |  |  |
| ISO 13485:2016, para. 8.3:Nonconforming products |  |  | x |  |  |
| ISO 13485:2016, para. 8.4:Analysis of data |  |  | x |  |  |
| ISO 13485:2016, para. 8.5:Improvement |  |  | x |  |  |
| Reg. (EU) 2017/745, Chapter VII, Art. 83-86:Post-Market Surveillance |  |  | x |  |  |
| Reg. (EU) 2017/745, Chapter VII, Art. 87-90:Vigilance |  |  | x |  |  |

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