\*\* FREE PREVIEW VERSION \*\*

Thank you for downloading the free preview version of the ISO 13485 Internal Audit Toolkit.

**Appendix 1 – Internal Audit Checklist for ISO 13485 and in compliance with Article 10 of MDR 2017/745**

# Internal Audit Checklist for ISO 13485

Date of audit: [date]

|  |  |  |  |
| --- | --- | --- | --- |
| **ISO 13485 clause** | **Requirement of the standard** | **Compliant (Yes/No)** | **Evidence** |
| 4.1.1 | Are the processes necessary for the QMS determined, described, managed, and applied in the organization in compliance with ISO 13485:2016 and MDR/2017/745?  Did the organization establish continuous improvement of a Quality Management System that shall ensure compliance with MDR 2017/745 in the most effective manner and in a manner that is proportionate to the risk class and the type of device?  Has the organization established the strategy for regulatory compliance, including compliance with conformity assessment procedures? |  |  |
| 4.1.2 | Does the organization implement a risk-based approach to the control of the appropriate processes needed for the Quality Management System, and is there a sequence and interaction of processes?  Is the risk-based approach in accordance with the Annex 1 General Safety and Performance Requirements from MDR 2017/745? |  |  |
| 4.1.3 | … |  |  |
| 4.1.4 | … |  |  |
| 4.1.5 | … |  |  |
| 4.1.6 | … |  |  |
| 4.2.1 | … |  |  |
| 4.2.2 | … |  |  |
| 4.2.3 | … |  |  |
| 4.2.4-01 | … |  |  |
| 4.2.4-02 | … |  |  |
| 4.2.4-03 | … |  |  |
| 4.2.4-04 | … |  |  |
| 4.2.4-05 | … |  |  |
| 4.2.5 | … |  |  |
| 4.2.5-01 | … |  |  |
| 5.1-01 | … |  |  |
| 5.1.-02 | … |  |  |
| 5.2 | … |  |  |
| 5.3 | … |  |  |
| 5.4.1 | … |  |  |

…

\*\* END OF FREE PREVIEW \*\*

If you have decided that the ISO 13485 Internal Audit Toolkit is the right choice for your company, please see the table below to choose the toolkit with the required expert support level.

|  |  |  |
| --- | --- | --- |
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|  | **US $197** | **US $697** |
| **5 document templates compliant with ISO 13485:2016** | **🗸** | **🗸** |
| **Email support** | 10 questions per month | Unlimited |
| **One-on-one support with an ISO 13485 expert** | 1 hour | 5 hours |
| **Expert review (completed documents)** | 1 document | 5 documents |
| **Pre-audit check** | **X** | **🗸** |
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