

Audit Plan

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| Date of the Audit | |
| Time | |
| Scope of the Audit | |
| Lead-Auditor | |
| Co-Auditor | |
| Auditee | |

The main purpose of the audit will be to evaluate the Quality Management System and to establish objective evidence that employees adhere to the procedures in place.

The audit criteria will include

- German MPDG,
- ISO13485:2016,
- 93/42/EEC as amended by 2007/47/EC,
- EU 2017/745 (MDR),
- MDSAP
 - Canadian Medical Devices Regulations (SOR/98 – 282)
 - United States FDA Quality System Regulation (21CFRPart 820, 801, 803, 806, 821, 830)

| Time | Criteria | Topics |
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