Interner Auditbericht

Auditdatum *(Date of the Audit)*:	
Zeit *(Time)*:	
Auditierter Bereich *(Scope of the Audit)*:	
Lead-Auditor:	
Co-Auditor:	
Auditteilnehmer *(Auditee)*:	

Auditunterlagen *(Audit documentation and regulations)*:	• German MPDG,
	• ISO 13485:2016,
	• 93/42/EEC (MDD),
	• 2017/745 (MDR),
	• MDSAP
	  ○ Canadian Medical Devices Regulations (SOR/98 – 282)
	  ○ United States FDA Quality System Regulation (21CFRPart 820, 801, 803, 806, 821, 830)

1. Goal
Describe briefly the scope and the focus of the audit

2. Observations and non-conformities from previous audits
(Observations and non-conformities from previous audits shall be reviewed. State if all actions were *completed and effective.)*

3. Audit results
(Describe the results of the audit. Provide objective evidence for the reviews done and observations or non-conformities made. This may be numbers of work instructions, records, equipment, products, batches. This data will simplify resolution and reduce discussions after the audit. Audit results have to be objective and clear, written without emotions.)

4. Executive Summary
(Summarize the audit result and list again all observations, non-conformities and recommendations made. The summary may include recommendations for the time of the next audit.)

Freigabe	
	name / date / signature
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