Risk Management Report	
Project/Product	*Document number, version, date*

Scope	*Scope of the risk management report*
Risk Management Process, Acceptance Criteria	*This Risk Management Report was written as per SOP Risk Management. It follows the requirements given in ISO 14971:2019 with special consideration of additional requirements from (EU) 2017/745. Risk acceptability criteria for both individual risks and overall residual risks are given in SOP Risk Management.*

Risk Management Activities	**Evidence of completion**
RISK MANAGEMENT PLAN *Risk Management was planned as per ISO 14971:2019 with special consideration of additional requirements from (EU) 2017/745. The Risk Management Plan was generated in accordance to SOP Risk Management.*	*Identify documents*
RISK ANALYSIS ON SYSTEM LEVEL *Risk Analysis on system level was generated in accordance to SOP Risk Management. System level risk analysis focussed on the usage of the entire therapy system under real use conditions.*	*Identify documents*
RISK ANALYSIS ON PRODUCT LEVEL *Risk Analysis on product level was generated in accordance to SOP Risk Management. Product level risk analysis focussed on the design of the medical device including packaging and labeling.*	*Identify documents*
RISK ANALYSIS ON PROCESS LEVEL *Risk Analysis on Process level was generated in accordance to SOP Risk Management. Process level risk analysis focussed on the manufacturing processes including shipping and storage.*	*Identify documents*
BIOLOGICAL EVALUATION *Biological evaluation as per ISO 10993-1:2018 was planned and conducted.*	*Identify documents*
USABILITY FILE *As per IEC 62366-1:2015, usability considerations were performed.*	*Identify documents*
CLINICAL EVALUATION *A clinical evaluation as per IMDRF MDCE WG/N56FINAL:2019 with special consideration of the requirements from article 61 and annex XIV of (EU) 2017/745 MDR, including PMCF, was planned and conducted.*	*Identify documents*
VERIFICATION OF RISK CONTROL MEASURES *It was verified, that all Risk Control Measures resulting from the Risk Analyses were implemented and shown to be effective.*	*Identify documents*
RISK MANAGEMENT REVIEW *Risk Management Review was conducted and documented.*	*Identify documents*
COLLECTION AND REVIEW OF RELEVANT PRODUCTION AND POST-PRODUCTION INFORMATION *Within the development phase, data from design verification, design validation as well as process validation activities was collected and evaluated. Data from post market phase is being collected and evaluated as per SOP PMS.*	*Identify documents*

Evaluation of overall residual risk	It is confirmed that any individual residual risks was reduced as far as possible and residual risks are disclosed. The implementation and effectiveness of any implemented risk control measure was verified. Clinical risks and clinical benefits were assessed within the clinical evaluation. A positive benefit-risk analysis was concluded within the clinical evaluation and therefore the overall residual risk is deemed acceptable. Or There are risks in the unacceptable regions and/or risks are not yet reduced as far as possible. Further risk control activities are needed.

Approval	
R&D	*name / date / signature*
QA/RA	*name / date / signature*