Risk Management Plan	*Document number, version, date*

Scope	*Scope and Out of Scope of the Risk Management Plan* *Lifecycle/Phase*
Risk Management Process, Acceptance Criteria	*This Risk Management Plan 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.*
Assignment of roles, responsibilities and authorities	*Risk Management team members* *Approval & signature requirements are given in SOP Risk Management*

Risk Management Activities	**Responsible person**	**Time plan**
RISK ANALYSIS ON SYSTEM LEVEL System level risk analysis will focus on the usage of the entire therapy system under real use conditions.		
RISK ANALYSIS ON PRODUCT LEVEL Product level risk analysis will focus on the design of the medical device including packaging and labelling.		
RISK ANALYSIS ON PROCESS LEVEL Process level risk analysis will focus on the manufacturing processes including shipping and storage		
BIOLOGICAL EVALUATION Biological evaluation as per ISO 10993-1 will be planned and conducted.		
USABILITY FILE As per IEC 62366-1, usability considerations will performed.		
CLINICAL EVALUATION Clinical evaluation with special consideration of the requirements from article 61 and annex XIV of (EU) 2017/745 MDR, including PMCF, will be planned and conducted.		
VERIFICATION OF RISK CONTROL MEASURES It is to be verified, that all Risk Control Measures resulting from the Risk Analyses were implemented and shown to be effective.		
RISK MANAGEMENT REVIEW Review of the Risk Management Activities will be conducted during the Risk Management Review and documented within the Risk Management Report.		

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 will be collected and evaluated. Data from post market phase will be collected and evaluated as per SOP PMS. Results will be reported within the continuous updates of the Risk Management Report.		

The documentation of the Risk Management process will be included or referenced within the Risk Management File.

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