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

Scope	*Scope of the risk management file*

Part I: Contents of Risk Management File

1. 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. The plan is referenced in part II of this Risk Management File.

2. 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. The analysis is referenced in part II of this Risk Management File.

3. 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. The analysis is referenced in part II of this Risk Management File.

4. 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. The analysis is referenced in part II of this Risk Management File.

5. Biological Evaluation

Biological evaluation as per ISO 10993-1 was planned and conducted. The results are included in section 6.1(b) of the technical documentation as per SOP Technical Documentation

6. Usability File

As per IEC 62366-1, usability considerations were performed. The results are documented in the clinical evaluation and analyses on system and product level. Addition, usability documents were written as per IEC 62366-1, documented as per SOP Design Control and referenced in Part II of this RMF.

7. Clinical Evaluation

A clinical evaluation with special consideration of the requirements from article 61 and annex XIV of (EU) 2017/745 MDR, including PMCF, was planned and conducted. Documents are referenced in Part II of this RMF.

8. Risk Management Report

Risk Management reviews were conducted as per ISO 14971:2019 and documented in accordance to SOP Risk Management. The report is referenced in part II of this Risk Management File.

Approval	
Risk Management Owner	*name / date / signature*
QA/RA	*name / date / signature*

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

Part II: Overview of Risk Management Activities

Document	**Status / Change**	**Reference**	**(Autor/Date/Signature)**
Risk Management Plan			
Risk Analysis on system level			
Risk Analysis on product level			
Risk Analysis on process level			
Biological Evaluation	The results are included in section 6.1(b) of the technical documentation as per SOP Technical Documentation		
Usability documents			
Clinical evaluation including PMCF	The results are included in section 6.1(c) and (d) of the technical documentation as per SOP Technical Documentation.		

Document	Status / Change	Reference	(Autor/Date/Signature)
Risk Management Report			