Risk Management Plan	Supplemental Risk Management Plan for the *component* subassembly, revision 1

Scope	This document will establish a supplemental Risk Management Plan for the *component* subassembly (manufactured for *supplier*) as defined within the Quality System Agreement *supplier-manufacturer*. It is a supplement to the overall Risk Management Plan for the *medical device* system.
Risk Management Process, Acceptance Criteria	This Risk Management Plan is generated in accordance to ISO 14971:2019 and in alignment to SOP Risk Management (*supplier*) and SOP Risk Management (*manufacturer*). • As different legal entities and therefore different Quality Management Systems will revert to this Risk Management Plan, definitions will be taken from ISO 14971:2019. Definitions and data sources applied, are listed in Annex 1 to this Risk Management Plan. • Ratings used for severity of harm are given in annex 2. • Ratings used for occurrence are given in annex 3. • Ratings used for detectability are given in annex 4. • Risk acceptability criteria are given in annex 5.
Assignment of roles, responsibilities and authorities	To accomplish all risk management activities, a risk management team was established. The following persons from *supplier* were assigned as risk management team members: • Production Engineer, *supplier* • Quality Engineer, *supplier* • Development, *supplier* Additional resources may be consulted as needed. The development function of the *manufacturer* will coordinate all activities regarding • specifications and failure modes, • hazardous situations and harms, • severity and probability of occurrence of harm. The risk management team members are mandatory reviewer and approvers of the risk management activities within this risk management plan.

Risk Management Activities	**Responsible person**	**Time plan**
RISK ANALYSIS ON SYSTEM LEVEL	The Risk Analysis for the final finished *medical device* system is out-of-scope of this Risk Management plan and is in responsibility of *manufacturer*.	
RISK ANALYSIS ON PROCESS LEVEL	A Process Risk Analysis (PFMEA) will be established assessing the risks of production of the *component* subassembly at supplier.	**September 2021**
VERIFICATION OF RISK MANAGEMENT ACTIVITIES	Traceability to all production control measures will be given within the PFMEA. Review of PFMEA will include verification, that production control measures were implemented.	**September 2021**
RISK MANAGEMENT REPORT	Risk Management report for the final finished *medical device* system is out-of-scope of this Risk Management Plan and is in responsibility of *manufacturer*.	
VERIFICATION OF EFFECTIVENESS OF RISK MANAGEMENT PROCESS	The effectiveness of the production risk control measures will be validated by continuous monitoring of production and post-production information. An initial review will be established within the approval of PFMEA.	**September 2021**
	The effectiveness of the Risk Management process for the final finished *medical device* system is out-of-scope of this Risk Management Plan and is in responsibility of *manufacturer*.	
COLLECTION AND REVIEW OF RELEVANT PRODUCTION AND POST-PRODUCTION INFORMATION	*Supplier* will collect and evaluate production and post-production information as defined in *supplier* Quality Manual	n/a, continuous activities
	The collection and evaluation of production and post-production information for the final finished *medical device* system is out-of-scope of this Risk Management Plan and is in responsibility of *manufacturer*.	
RISK MANAGEMENT FILE	The Risk Management file for the final finished *medical device* system is out-of-scope of this Risk Management plan and is in responsibility of *manufacturer*.	

Approval	
Function	*name / date / signature*
Production Engineer, *Supplier*	
Quality Engineer, *Supplier*	
Development, *Manufacturer*	
Quality Management Representative, *Supplier*	
Quality Management Representative, *Manufacturer*	

Annex 1	Definitions and source of data

Definitions, where possible, will be taken from ISO 14971:2019

Term	Definition	Source of data	Notes
Harm	injury or damage to the health of people, or damage to property or the environment	*Manufacturer* as owner of the final finished product will determine the applicable list of harms	Approval of this risk analyses will document *manufacturer* approval of list of harms
Hazard	potential source of harm	Baseline for a list of hazards is given within table C.1 of ISO 14971:2019	-
Hazardous situation	circumstance in which people, property, or the environment are exposed to one or more hazard(s)	*Manufacturer* as owner of the final finished product will determine the applicable list of hazardous situations	Approval of this risk analyses will document *Manufacturer* approval of list of hazardous situations
Risk	combination of the probability of occurrence of harm and the severity of that harm	-	-
Severity	measure of the possible consequences of a hazard	*Manufacturer* as owner of the final finished product will determine the applicable severity ratings	Approval of this risk analyses will document *Manufacturer* approval of list of severity ratings. Severity ratings are listed in Annex 2 of this Risk Management Plan.
Occurrence of harm	probability of occurrence of harm	*Manufacturer* as owner of the final finished product will determine the applicable occurrences	Approval of this risk analyses will document *Manufacturer* approval of occurrences of harm. Occurrence ratings are listed in Annex 3 of this Risk Management Plan
Occurrence of failure	probability of occurrence of failure	*Supplier* will establish the occurrence of failure based on historical process data	Occurrence of failure is to be differentiated from occurrence of ham. Occurrence ratings are listed in Annex 3 of this Risk Management Plan.

Term	Definition	Source of data	Notes
Detectability of failure	probability of detection of failure before the final finished product will be placed on the market	*Supplier* will determine the detectability of failure based on historical process data	Detectability ratings are listed in Annex 4 of this Risk Management Plan.

Annex 2	Severity ratings

As different legal entities and therefore different Quality Management Systems will revert to this Risk Management plan, an alignment of two different systems for severity ratings is needed.

The following table shows the alignment of both systems.

Supplier		***Manufacturer***	
Severity	**Description**	**Severity**	**Description**
10		5	
9		4	
8			
7		3	
6		2	
5		1	
4			
3			
2			
1			

Annex 3	Ratings for Occurrence

As different legal entities and therefore different Quality Management Systems will revert to this Risk Management Plan, an alignment of occurrence ratings is needed.

- *Manufacturer* will apply occurrence ratings for **harm**
  - These occurrence ratings are to be understood as probability of occurrence of harm.

- *Supplier* will apply occurrence ratings for **failure**
  - These occurrence ratings are to be understood as occurrence of failure.
  - Probability of occurrence of failure is to be communicated as such to *manufacturer*.

The following table shows the alignment of both systems.

Supplier		***Manufacturer***	
Occurrence	**Description**	**Occurrence**	**Description**
10		5	
9			
8			
7		4	
6			
5			
4		3	
3			
2			
1		2	
		1	

Annex 4	Ratings for Detectability

As different legal entities and therefore different Quality Management Systems will revert to this Risk Management plan, an alignment of detectability ratings is needed.

- *Manufacturer* will not apply detectability ratings.
- *Supplier* will apply detectability ratings
    - These detectability ratings are to be understood as detectability of the failure.

The following table shows the alignment of both systems.

Supplier		***Manufacturer***	
Detect-ability	**Description**	**Detect-ability**	**Description**
10		5	n/a
9		4	n/a
8		3	n/a
7		2	n/a
6			
5			
4			
3			
2		1	n/a
1			

Annex 5	Risk Acceptance Criteria

As *manufacturer* is responsible for the final finished *medical device* system, the applicable risk acceptance criteria from *manufacturer* will be applied.