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Logo manufacturer	**Risk Analysis Table**	Revision: x.x
Product(s) or trade name(s) / *product group/family*		

Risk ID	Hazard	Harm	Risk	Risk reduction measures	Verification of the	Residual risk	New risks due to risk reduction measures
R1							
R2							

P = probability of occurrence; S = severity; R = risk range (h = high, l = low).

Please fill in table with all identified (potential) risks to the production and the device itself and expand for this purpose if necessary.

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Logo manufacturer	**Risk Analysis & Risk Management Report**	Revision: x.x
Product(s) or trade name(s) / *product group/family*		

Releases:

	Date	**Name**	**Signature**
Quality manager	YYYY-MM-DD		
Released Management:	YYYY-MM-DD		
Author (just name)**:**			

Document history:

Revision	**Date**	**Description of the change**
x.x	YYYY-MM-DD	

1 Scope

☐ This risk analysis and risk management report are applicable to the medical devices listed in the associated risk management plan (Risk Management Plan xxx, dated/version xxx).

☐ Other, subject of the risk analysis:

Text box for explanations

2 Reason for risk assessment

☐	Design & Development, Phase:	
☐	Input from PMS activities:	
☐	Changes in the state of the art:	
☐	Product modification:	
☐	Changes in processes after development:	
☐	Corrective and preventive action:	
☐	Notifications of incidents and new risks:	
☐	Other:	

Please briefly explain reason in the corresponding line of the right column

3 Risk analysis

☐ The risk analysis was performed according to the risk management plan (see Section **Fehler! Verweisquelle konnte nicht gefunden werden.**).

☐ The risk analysis was performed according to:

Text box for explanations

3.1 Risk analysis table

Based on the manufacturing process, product design and intended purpose, any risks were identified that are related to the intended purpose, foreseeable misuse and other characteristics related to product safety.

The potential harms were assigned to the corresponding hazard situations and sources of harm. The most severe potential consequence in the event of harm (severity) was then assessed and the probability of occurrence estimated. With these evaluations, the risk matrix (see associated RM plan) was used to determine the general risk = basic risk.

The result divides the basic risk resulting from the source of harm into the risk ranges: "high" (unacceptable) or "low" (largely acceptable). According to these categories, the type of mitigation measures to be applied (design change/modification in manufacturing, protective feature in the device, protective measures in processes and/or safety information) could be selected. The residual risk resulted from the achieved reduction of the basic risk due to the effect of the mitigation measures.

The overall residual risk has been assessed as acceptable. The final verification of the risk control measures is carried out with this risk management report.

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Logo manufacturer	**RM Plan** Risk Management Plan	Revision: x.x
Product(s) or trade name(s) / *product group/family*		

Releases:

	Date	Name	Signature
Quality manager	YYYY-MM-DD		
Released Management:	YYYY-MM-DD		
Author (just name)**:**			

Document history:

Revision	Date	Description of the change
x.x	YYYY-MM-DD	

1 Scope

This plan is applicable to the following medical devices:

Table 1: Medical devices applicable to the plan

Product(s) or trade name(s) / product group/family			
Item no.	**Designation**	**Intended purpose *1**	**Current life cycle phase *2**

*1 The intended purpose should take into account information such as intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle. (EN ISO 14971:2019 + A11:2021)

*2 z.B. indication of development phase or production and post-production phase.

The risk management plan refers to product risk activities and documentation. The scope of risk management is limited to the medical devices mentioned above, the interface with other devices and the intended purpose stated by the manufacturer.

2 Responsibilities and authorities

Table 2: Responsibilities and authorities

Responsibilities / risk management activities	**Function**	**Assigned person(s)**
Release of risk management	Management	
Determine risk management team and team leader (TL).	Management	
Defining acceptance criteria for risk management in line with risk policy	Risk management team	
Risk management plan	Risk management team	
Risk analysis – Description of the intended purpose and reasonably foreseeable misuse – Identification of the characteristics that are related to safety – Identification of associated hazards and hazardous situations – Estimation of risks for each hazardous situation	Risk management team	
Risk assessment	Risk management team	

Responsibilities /	Function	Assigned person(s)

longer acceptable are to be identified. Internal feedback is also reviewed as part of the CAPA process.

The results are recorded in the analysis and assessment documents in accordance with the PMS plan and the CAPA forms (in accordance with standard operating procedure xxx). If an

Table 4: Determination of probability of occurrence (P), qualitative level of probability of occurrence (related to xy times product is used, which is equal to sales of the product per year / which is equal to sales of xy products per year) *An explanation applicable to the device should be provided*

Common terms		**Probability range**
Frequent	A5	> 1 out of 100 ($p > 10^{-2}$)
Probable	A4	≤ 1 out of 100 ($p \leq 10^{-2}$)
Occasional	A3	≤ 1 out of 1000 ($p \leq 10^{-4}$)
Remote	A2	≤ 1 out of 10.000 ($p \leq 10^{-6}$)
Improbable	A1	≤ 1 out of 100.000 ($p \leq 10^{-8}$)

Table 5: Risk matrix, semi-quantitative 5x5 matrix

		Severity				
		S-1	**S-2**	**S-3**	**S-4**	**S-5**
Occurrence probability	**P-5**					
	P-4					
	P-3					
	P-2					
	P-1					

If a probability of occurrence cannot be estimated, a list of possible consequences is drawn up. In determining the probability, the possible harm and the severity of the harm are considered. Information is taken from the following sources, for example:

- published standards
- scientific or technical investigations
- Market data on similar medical devices already in use, including publicly available incident reports
- usability tests with typical users
- clinical evidence
- results of relevant investigations or simulations
- expert reports

After evaluation of the acceptance criteria, the risk under consideration is assigned to either a "high" or "low" risk range (see Table 6).

1. In the "high" range are the unacceptable risks related to the complete risk management process.

2. Notwithstanding point 1, the range "high" can be accepted if the benefit-risk analysis determines that the medical benefit outweighs the remaining risk

Table 7: Differentiated risk matrix for overall residual risk assessment

Internal feedback (e.g. from production) is also recorded and reviewed as part of the CAPA process (standard operating procedure xxx) with regard to aspects relevant to product safety.