

Risk Analysis	Document number / Version
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Approvals	<i>Name / Date / Signature</i>
	Risk Management Owner
	R&D
	QA/RA
	Manufacturing
	Medical
	Sales / Marketing

Type of Risk Analysis	<input type="checkbox"/> Hazard Analysis
	<input type="checkbox"/> System Level
	<input type="checkbox"/> Product Level
	<input type="checkbox"/> Process Level

Referenced Documents	<i>Document number /version / Title</i>
	Risk Management Plan
	PMS Report / PSUR
	Clinical Evaluation

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Intended Use	<i>Describe the intended use of the system/product/process</i>
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Approach and Risk Acceptability criteria	<p>This risk analysis was generated in accordance to SOP Risk Management. Roles, responsibilities, approval requirements are given in SOP Risk Management.</p> <p>A 2-dimensional risk evaluation approach was chosen as per SOP Risk Management, using</p> <ul style="list-style-type: none">• Severity ratings (S) as per table 1 of SOP Risk Management• Occurrence ratings (O) as per as per table 2 of SOP Risk Management• Risk Acceptability criteria are given in table 3 of SOP Risk Management.
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Risk Analysis, Control and Evaluation

System level:

Potential Harms	Potential Causes (Hazardous Situations)	System Elements								Cause of Failure	Risk Control Measures	Severity (S)	Occurrence (O)	Risk Evaluation	Remarks
		Hardware	Software	Disposable 1	Disposable 2	Disposable 3	Disposable 4	Accessory 1	Accessory 2						
				X											

Legend:

"X" in the table below means that the potential cause of failure could be caused by the element checked.

Note: Instead of listing systems elements horizontally, one could also list them vertically as first column in the table. Additional columns may be added, if required.

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Product level:

Potential Harms	Potential Causes (Hazardous Situations)	Product components							Cause of Failure	Risk Control Measures	Severity (S)	Occurrence (O)	Risk Evaluation	Remarks
		Housing 1	Housing 2	Inlets	Outlets	Inlays	xxx	xxx						
				X										

Legend:

"X" in the table below means that the potential cause of failure could be caused by the components checked.

Note: Instead of listing product components horizontally, one could also list them vertically as first column in the table. Additional columns may be added, if required.

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Process level:

Potential Harms	Potential Causes (Hazardous Situations)	Process steps								Cause of Failure	Risk Control Measures	Severity (S)	Occurrence (O)	Risk Evaluation	Remarks
		Moulding	Welding	Cutting	Leak test	Sterile packaging	Final packaging	Transport	Sterilization						
				X											

Legend:

"X" in the table below means that the potential cause of failure could be caused by the process steps checked.

Note: Instead of listing process steps horizontally, one could also list them vertically as first column in the table. Additional columns may be added, if required.

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List of Risk Control Measures

Number	Risk Control Measure	Reference	Note

Risks arising from Risk Control Measures

- None of the risk control measures above generated an additional potential hazard.
- The following risk control measures stated above have generated additional potential hazards:

Conclusion

- It is confirmed that there are no unacceptable risks and any risk in the ALARP region is reduced as far as possible.
- Or**
- There is/are risk(s) in the unacceptable regions and further risk control measure is required.