Risk evalution Processes

Process Name

	Risk Categories						
Probability of Occurrence	5	5	10	15	20	25	
	4	4	8	12	16	20	
	3	3	6	9	12	15	
	2	2	4	6	8	10	
	1	1	2	3	4	5	
		1	2	3	4	5	
	Severity	1-Negligible	2-Minor	3-Moderate	4-Critical	5-Catastrophic	

Total score

1-6	Broadly acceptable
7-12	Acceptable risk - maybe further investigation
13-25	Intolerable risk

Identify the risks in the process	Probability	Severity	Score	Corrective acti	Probability	Severity	Score	Conclusion
Total								

Definition of the risk

The risk in a process is a parameter that can have a negative effect on following:
Safety and performance of the medical device
Meeting the regulatory requirements
Meeting the quality goals of OM

Calculating the score:

Risk category x Severity = Score

Risk evaluation based on the principles in EN ISO 14971

Date:
Responsible: