2.2 Risiko - Assessment
2.2.3 Risiko - Assessment with FMEA

DQ

	Customer:	Machine:	Participants see Change History	*) H= High, M= Medium, L=Low	Date:	Version	Date:	Version
sortimat besser. innovativ. schneller	KD-Name	Assembly machine for			01. Jul 05			

Station Nr.	Function Type	Sub-Function	Risk Scenario	Relevanz: GxP – Patient (Product quality)	Relevanz: GxP – Operator (Machine safety)	Relevanz: GxP – Third Person (Safety at product use)	Relevanz: Business	Potential Effect(s)	Likelihood*)	Impact*)	Risk Class*)	Prevention or Detektion	Probability of Detektion*)	Priority	Recommended Action(s)	Responsibility:	Reassessment (only if actions): Action Results	Likelihood*)	Impact*)	Risk Class*)	Probability of Detektion**)	Priority	Verification [IQ/OQ, FAT/SAT]