Risk Management Process



Risk Management Plan



Risk Analysis

Risk Assessment



Risk Evaluation



Risk Control



Evaluation of Overall Risk Acceptability



Risk Management Report



Production & Post-Production Information

Define Intended use

Identify all risk management activities

Define roles and responsibilities

Define criteria for product's risk acceptability

Specify methods to verify the implemen-tation of risk control measures

Define how post-production information will be captured Specify the intended use

Identify hazards

Define

hazardous situation and foreseeable sequences of exects

Estimate risk based on the severity and occurrence of the harm Use the risk Acceptability Matrix

Check that risks levels are acceptable

Consider:

Inherent safety by design

Protective measures in the actual medical device and/or manufacturing process

Information for safety, such as labeling and instruction for use

Check the residual risks, if the risk level is

acceptable

Provide a risk/ benefit analysis for all risks

Reduce as far as possible all risks Verify that all the steps provided in the risk management plan are completed

Summarize all risk management activities including Risk benefit analysis

Takes risks from production and post-production into account Consider and document production related risk management activities and events

Ensure that post-production processes include in QMS are feeding into Risk Management Process

Tile complaints, customer feedback, nonconformances, CAPAs into Risk Management

Medical Device Risk Management Plan Template

Xiang Xie

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