Risk mgt policy
1. Create Risk Management Plan
2. Identify Hazards, Hazardous situations
RISIKO MANAGEMENT
3. Conduct Risk Analysis + initial risk evaluation
4. Define Risk Control Measures + final Risk Evaluat.
5. Create Risk Management Report
"CER"
clinical evaluation
Summative usability
Form. Usability Test reports
5. Conduct MD validation activities
Prä-Klinik
Safety certificates
4. Conduct verification activities
manufacturing process
safety features
3. Develope device design
ENTWICKLUNG
Essential Performance
Clinical relevant performance
safety requirements
Req. from RM
Usability Specs
performance requirements
2. Derive System/Software/component requirements
regulatory requirements
USER NEEDS
1. Define: Intended purpose, user needs, stakeholder requir.
Produktbeschreibung
intended use
-"- user
-"- patients
Indication / Contraindication
Intended patients
intended users
5. Conduct Update of Clinical Evaluation (PMCF)
PMS
4. Create Clinical Evaluation Report
KLINISCHE BEWERTUNG
3. Assess & Analyse identified clinical data sets
"CER"
Zusammenfassung Referenz Verifiz. Tests
Benefit / Risk Analysis
Risk Management Report
2. Identify Clinical Data Sets: - Literature Review - PMS data - Clinical investigations
CV - Assessor
Clinical Data Assessment Report
Literature Search Protocol
Studien Einreichunterlagen
Product Specific
1. Create Clinical Evaluation Plan
Intended Patients

1. Define: Intended Purpose, User needs, stakeholder requir.

2. Derive System / Software / component requirements

ENTWICKLUNG

3. Develope device design

4. Conduct verification activities

5. Conduct MD validation activities

7. Create Risk Management Plan

Risk Mgt pol...

USER NEEDS

performance requirements

ESSential Performance

safety features

safety certificates

clinical evaluation

regulatory requirements

Klinische / reg. Strategien.

Clinical relevant performance

manufacturing process

prä - Klinik

Summative usability (62366)

Nutzen / Claims

safety requirements

Form. Usability Test reports

Reg. from RM

Usability Specs

System requirement.

Design Input, Spezifikation.

Device Description (Draft)

1. Create Clinical Evaluation Plan

2. Identify Clinical Data Sets:
- Literature Review
- PMS data
- Clinical Investigation

KLINISCHE BEWERTUNG

3. Assess & Analyse identified clinical data sets

4. Create Clinical Evaluation Report

5. Conduct Update of Clinical Evaluation (PMCF)

Intended Patients

Intended users

Indication

Define Evaluation Criterias

klinische / regulatorische Strategie

NUTZEN / Claims

Literature Search Protocol

Studien Einreichunterlagen

Product Specific PMS + PMCF Plan

CV - ~~Assor~~ Assessor

Clinical Data Assessment Report

"CER"

Zusammenfassung / Referenz / Verifiz. Tests

Benefit / Risk Analysis

Risk Management Report

PMS

klinisch relevante Risiken

REQ. FROM RM

klinisch relevante Leistungsparameter

Ethikvotum

clinical evaluation

5. Evaluation activities

Produktbeschreibung

Intended purpose

intended users

1. Create Risk Management Plan

RISIKO MANAGEMENT

2. Identify Hazards, hazardous situations

3. Conduct Risk Analysis + initial risk evaluation

4. Define Risk Control Measures + final Risk Evaluat.

5. Create Risk Management Report

1. Create Clinical Evaluation Plan

Intended Patients

Risk mgt policy

acc. criteria

Responsabilities

manufactoring PROCESS

USE SPECIFICATION

Gefährdungs-analyse

foreseeable misuse

FMEA

Identified essential Performance

Requirements for Risk Control

"CER"

Benefit/Risk Analysis

Test Results from Development

PMS

Verify Risk Control Measures