

Services

CE
Documentation

Test Laboratory

References

PRO

DE

Back

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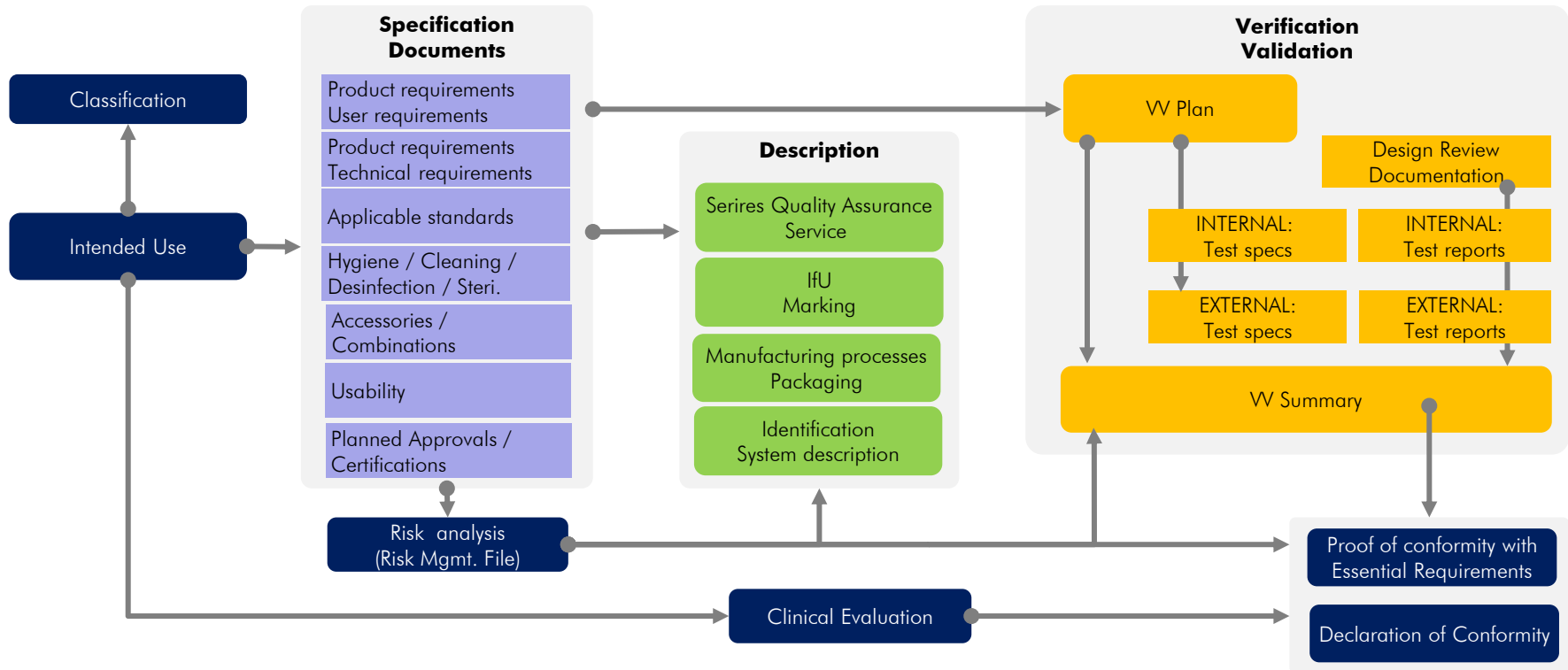
CE Documentation – Design History File

- Specifications
- Risk Management
- Clinical Evaluation
- Verification and Validation
 - Planning – Realization - Evaluation
- Conformity Assessment Procedure

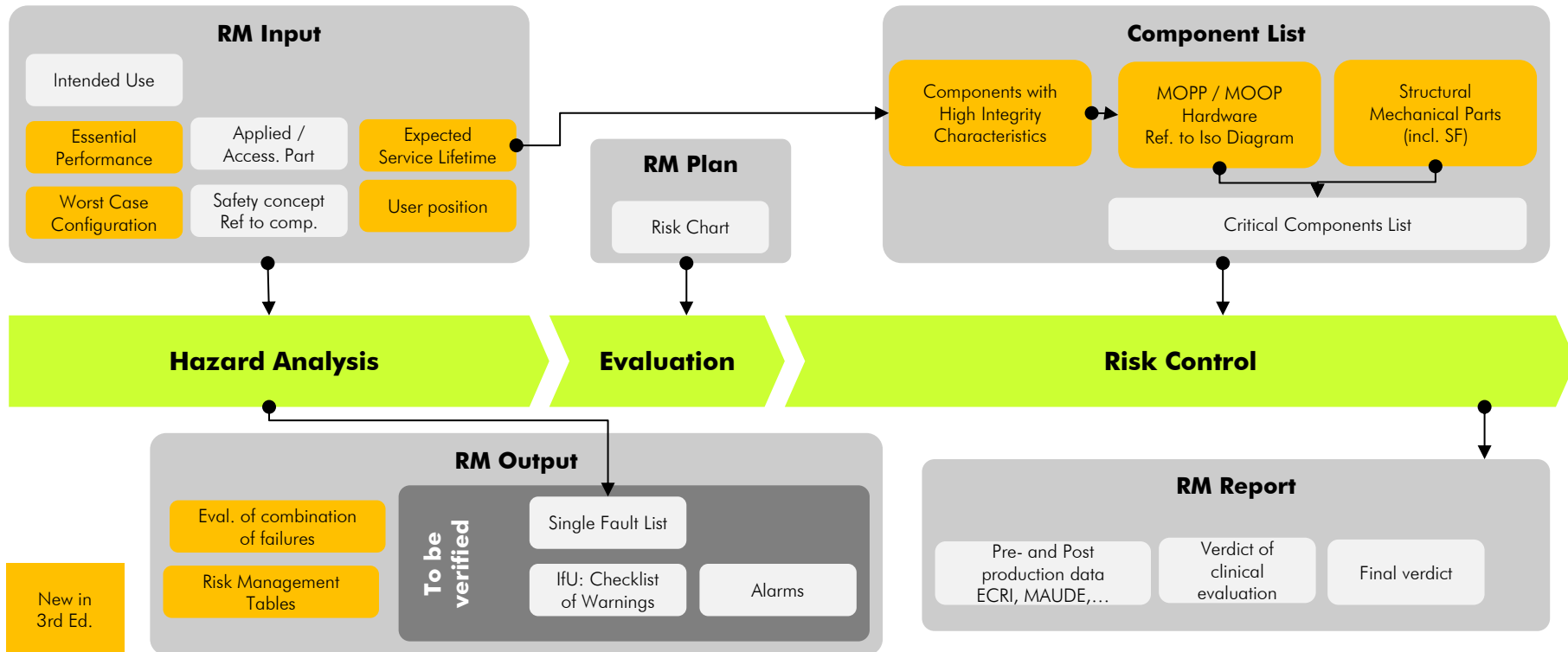
[Structure DHF](#)

[Risik mgmt. 3rd Ed.](#)

CE Documentation – Design History File



CE Documentation – Risk Management 3rd Ed.



New in 3rd Ed.

Test Laboratory

Verification

- Standard tests
- Specification verification
- Combination with other medical devices
- Combination with accessories

Validation

- Usability tests

Test management

Specification verification

Standard tests

Projects

Test Laboratory – Test Management

Coordination of tests in various test laboratories

- costs, timing, preliminary tests

NRTL tests

CB reports

Typ. 10300
Ser.-Nr.: 2 kN
Messb.: 2,282 mV/V
Signal

Test Laboratory – Specification verification

Performance
Reliability
Mechanical environmental simulations *)
Climate tests *)

Measured variables

- Length
- Displacement
- Temperature
- Humidity
- Weight
- Force
- Pressure
- Flow
- Electric variables

*) Tests in partner laboratories

Test Laboratory – Norm Tests

- DIN EN 60601-1 (Medical Devices)
- DIN EN 61010 (Laboratory Equipment)
- DIN EN 60601-2-x (Particular standards*)
- ISO 10993 (Biocompatibility *)

*) Tests in partner laboratories

Partial testing:

- Electrical Safety
- Markings, Documentation
- Mechanical Safety
- Rough Handling
- Temperature hazards
- Accuracy of Indicators
- PEMS

Project examples

- Ambulance trolley system
- Anaesthesia machine (MR-compatible)
- ECG (Holter recorder)
- Electrocardiograph (PC based)
- Emergency ventilator
- Extracorporeal shockwave lithotripter
- Image data processing system for pharmaceutical study
- Infusion pressure cuff
- Invasive tissue oxygen measurement
- IT system for remote control of intensive care ventilator
- Laryngoscopes
- Magnetic resonance coils
- Mechanical holder for infusion pumps and monitors
- Medical gas pressure reducer
- Neonatal intensive care incubators
- Neonatal radiant warmer
- Neonatal transport incubator system
- Non-invasive blood pressure measurement
- Oxygen supply cart
- SpO₂ measurement and sensors
- X-Ray "Bucky Unit"

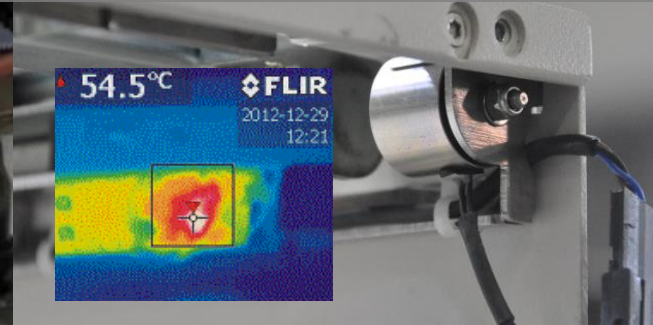


Techn. Changes: X-Ray

Device Re-design: ESWT

Update CE File: ECG

Project example – X-Ray component



CE Documentation: technical change

- Development of specifications
- Test planning
- Verification of specifications
- Norm tests with NRTL (CSA, CAN)
- Mech. environmental simulation (SNV, Climate)
- Endurance testing
- Thermal analysis (IR camera)

„The cooperation was very enjoyable and Qualitätsplan prepared the documentation very thoroughly and independently.“

R.T. – Project manager

Project example – Shockwave therapy device

„In collaboration with Qualitätsplan we had a very good ratio of external output to internal coordination efforts“

H.S. – Head of QM

CE Documentation: Device re-design

- Test planning
- Verification of specifications
- Standard tests in accredited test laboratory (CB Report)
- Mech. environmental simulation (SNV, Climate)
- Usability testing (60601-1-6)





Project example – ECG Recorder

3rd Edition Risk Management

- Revision of risk management
- Specification of required IfU additions

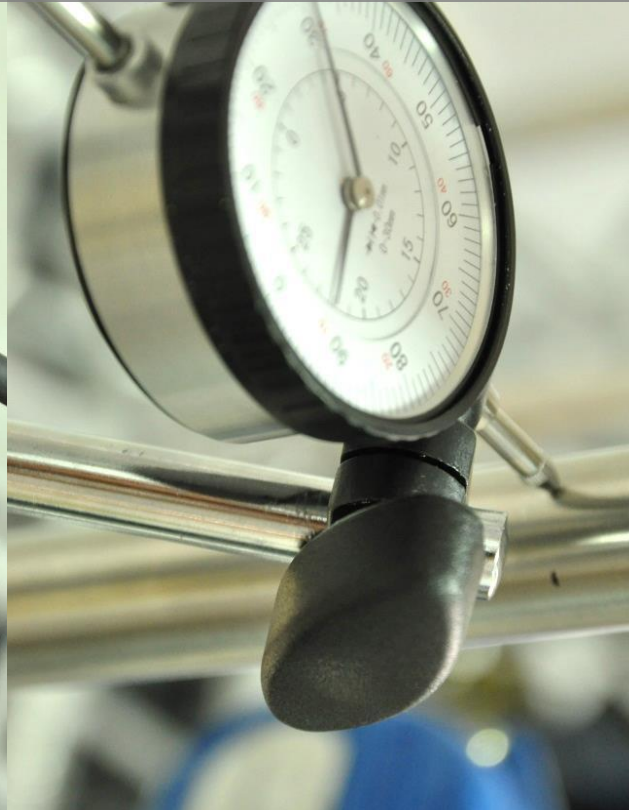
Update of Clinical Evaluation (PMCFUP)

- Scientific literature search
- Addition of new indications

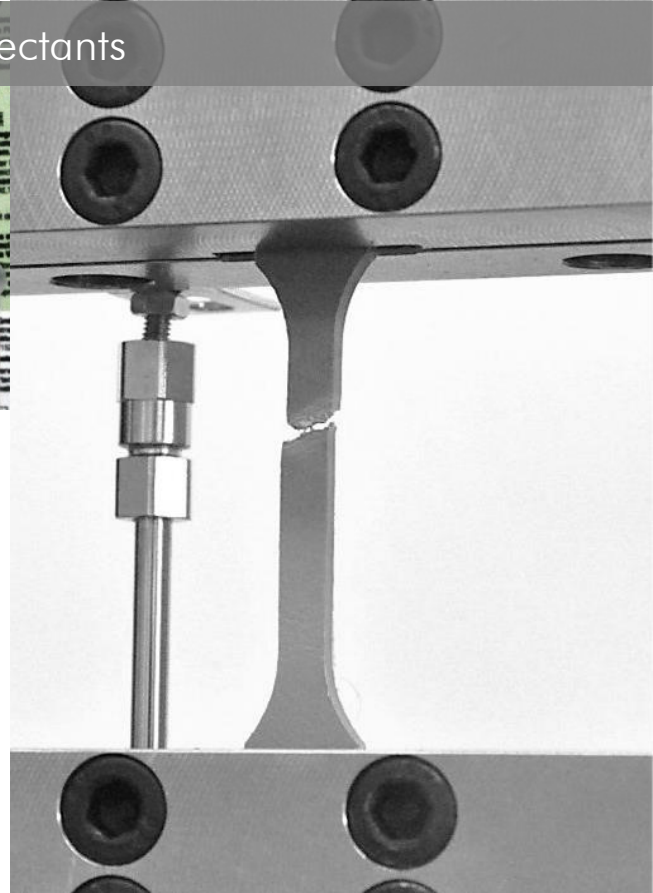
„In our opinion the documentation provided by Qualitätsplan is prepared with exactly the required level of detail.“

O.E. – Product Manager

Project example – Load test of accessories arm



Project example – Resistance of housing materials to disinfectants



4 housing materials

8 disinfectants

180 test samples

Tensile testing according to ISO 527

3rd Ed. RM



- ECG Recorder
- Infant incubator
- Shockwave therapy device
- Phototherapie
- Anaesthesia machine

Projects - International Approvals



- USA
 - 510(k) : standard procedure for medical devices
 - IDE : investigational device exemption
- Canada (Class 2 and 3)
- Singapore (Asean - CSDT)
 - “Common Submission Dossier Template” (CSDT).
- Mexico
- Korea

Work methods

Project goal

Structure
Methodology
Testing know-how
Standards
„Third-party“ perspective
Project management
Regulatory perspective
Application (partly)

Device design
Process
Application

Qualitätsplan

Customer



Quality policy

Communication –
clear and explicit

Documentation –
structured and simple

Work –
process- and goal-
oriented

Qualitätsplan –
an engineering service
provider

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