Clinical Evaluation Plan (chapter structure)

Approval

1 Meta information

- 1.1 Objective of this document
- 1.2 General safety and performance requirements
- 1.3 Procedure for clinical evaluation

2 Device

- 2.1 Intended purpose of the device
  - 2.1.1 Intended medical purpose
  - 2.1.2 Other normal use (optional)
- 2.2 Target groups
  - 2.2.1 Characterization of users
  - 2.2.2 Characterization of the patients
- 2.3 Indications
- 2.4 Contraindications
- 2.5 Claims

3 State of the art, clinical background, scientific validity

- 3.1 Identification of similar devices
- 3.2 State of the art – technology
- 3.3 State of the art – medicine
- 3.4 Standalone software: Proof of scientific validity
- 3.5 Summary of the state of the art
  - 3.5.1 Patient population, indication and contraindication
  - 3.5.2 Benefit
  - 3.5.3 Clinically relevant parameters
  - 3.5.4 Risks

4 Clinical benefit

5 Equivalence analysis

- 5.1 Identification of the equivalent device
- 5.2 Summary of the equivalence analysis

[1] For standalone software: verification of technical performance
[2] For standalone software: clinical validation