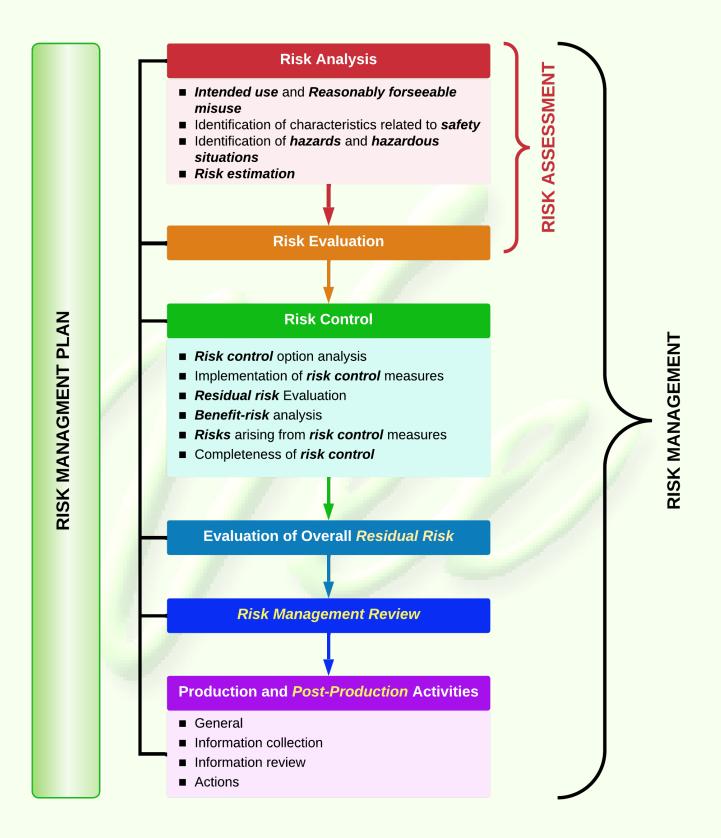
### **RISK MANAGEMENT PROCESS**



# D-722-3-2 RISK MANAGEMENT\_V1

## **RISK MANAGEMENT PLAN**

#### 1. SCOPE

2. DEVICE DESCRIPTIONS

- 3. PERSONNEL AND RESPONSIBILITIES
- **RISK MANAGEMENT PLAN** 4. RISK MANAGEMENT PROCESS
  - 5. RISK ANALYSIS PROCESS
  - 6. RISK EVALUATION PROCESS
  - 7. RISK CONTROL MEASURE PROCESS
  - 8. OVERALL RESIDUAL RISK
  - 9. VERIFICATION OF RISK CONTROL MEASURES
  - **10. RISK MANAGEMENT REVIEW**
  - **11. PRODUCTION AND POST-PRODUCTION ACTIVITIES**

## **RISK MANAGEMENT REPORT**

- **1. RESPONSIBLE PERSONNEL SIGNATURES**
- 2. SUITABILITY & EFFECTIVENESS OF RM PROCESS
- **3. ADEQUACY OF CRITERIA TO ACCEPT RISKS**
- 4. REPORTS ON DAMAGES, COMPLAINTS & SIDE **EFFECTS**
- **5. RESIDUAL RISKS CONNECTED TO THE PRODUCT**
- **RISK MANAGEMENT REPORT** 6. IEC60601-1 TRF VERDICT TABLE (ACTIVE DEVICE ONLY)

7. SUMMARY AND CONCLUSIONS