Summary Technical Documentation
STED

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Based on

- Summary Technical Documentation for Demonstrating Conformnity to the Essential Principles of Safety and Performance of Medical Devices (STED)
- GHTF/SGlINOll:2008
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  - Device Description
  - Product Specification
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- Essential Principles (EP) Checklist
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Device Description

- General description
  - intended use/purpose
  - intended patient population
  - medical condition to be diagnosed and/or treated
  - other considerations such as patient selection criteria
- Principles of operation
- Risk class and the applicable classification rule
- Explanation of any novel features
- Description of accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it

Device Description

- Various configurations/variants of the device that will be made available
- Key functional elements
  - its parts/components (including software if appropriate)
  - its formulation, its composition, its functionality
    - labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components
    - sufficient explanation to understand drawings and diagrams
- Materials incorporated into key functional elements
- Materials making either direct or indirect contact with the body, e.g., during extracorporial circulation of body fluids.

Product Specification

- List of the features, dimensions and performance attributes of the medical device
- Its variants and accessories
  - typically appear in the product specification made available to the end user
  - in brochures, catalogues and the like

Reference to similar and previous generations of the device

- Manufacturer’s previous generation(s) of the device
- Similar devices available on the local and international markets

Labelling

- Complete set of labelling associated with the device
- Labels on the device and its packaging
- Instructions for use
- Promotional material
- In a language acceptable to the reviewing RA or CAB

Design and Manufacturing Information

- **Device Design**
  - general understanding of the design stages applied to the device
  - not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity
  - information may take the form of a flow chart

- **Manufacturing Processes**
  - general understanding of the manufacturing processes
  - not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity
  - information may take the form of a process flow chart showing
    - overview of production, assembly, any final product testing, and packaging of the finished medical device.

- **Design and Manufacturing Sites**
  - identify the sites where these activities are performed
  - Annex QMS certificates

Essential Principles (EP) Checklist

- EP checklist that identifies
  - Essential Principles
  - whether each Essential Principle applies to the device and if not, why not
  - method(s) used to demonstrate conformity with each EP that applies
  - reference for method(s) employed (e.g., standard)
  - precise identity of the controlled document(s) that offers evidence of conformity with each method used

Essential Principles (EP) Checklist

- Methods used to demonstrate conformity
  - conformity with recognised or other standards
  - conformity with a commonly accepted industry test method(s)
  - conformity with an in-house test method(s)
  - evaluation of pre-clinical and clinical evidence
  - comparison to a similar device already available on the market
- Incorporate a cross-reference to the location of evidence
  - within the full technical documentation held by the manufacturer
  - within the STED

Risk Analysis and Control Summary

- Contain a summary
  - risks identified during the risk analysis process
  - how these risks have been controlled to an acceptable level
- Risk analysis should be based on recognised standards and be part of the manufacturer's risk management plan

Product Verification and Validation

- Summarise the results of verification and validation studies
  - engineering tests
  - laboratory tests
  - simulated use testing
  - any animal tests for demonstrating feasibility or proof of concept of the finished device
  - any published literature regarding the device or substantially similar devices

Product Verification and Validation

- Summary information
  - declaration/certificate of conformity
    - to a recognised standard(s)
    - summary of the data if no acceptance criteria are specified in the standard
    - to a published standard(s) that has not been recognised, supported by a rationale for its use, and summary of the data if no acceptance criteria are specified in the standard
    - to a professional guideline(s), industry method(s), or in-house test method(s), supported by a rationale for its use, a description of the method used, and summary of the data in sufficient detail to allow assessment of its adequacy
  - review of published literature regarding the device or substantially similar devices

Product Verification and Validation

- Describe test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions
- Detailed information
  - biocompatibility
  - medicinal substances incorporated into the device, including compatibility of the device with medicinal substance
  - biological safety of devices incorporating animal or human cells, tissues or their derivatives
  - sterilisation
  - software verification and validation
  - animal studies that provide direct evidence of safety and performance of the device, especially when no clinical investigation of the device was conducted
  - clinical evidence

Product Verification and Validation

- **Biocompatibility**
  - list of all materials in direct or indirect contact with the patient or user
  - tests conducted, standards applied, test protocols, analysis of data and summary of results
  - tests should be conducted on samples from finished, sterilised (when supplied sterile) device
- **Medicinal Substances**
  - provide detailed information concerning that medicinal substance, identity and source, intended reason for its presence, and its safety and performance in intended application
- **Biological Safety**
  - List all materials of animal or human origin used in the device
  - detailed information concerning selection of sources/donors; harvesting, processing, preservation, testing and handling of tissues, cells and substances of such origin
  - Process validation results to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents
  - System for record-keeping to allow traceability from sources to the finished device should be fully described

Product Verification and Validation

- **Sterilisation**
  - information of initial sterilisation validation including bioburden testing, pyrogen testing, testing for sterilant residues and packaging validation.
    - method used, sterility assurance level attained, standards applied, sterilisation protocol in accordance with those standards, and summary of results
  - evidence of the ongoing revalidation of the process
    - arrangements for, or evidence of, revalidation of the packaging and sterilisation processes
- **Software Verification and Validation**
  - information on software design and development process and evidence of validation of software
  - summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment
  - Address different hardware configurations and operating systems
- **Animal Studies**
  - describe study objectives, methodology, results, analysis and conclusions and document conformity with GLP
  - rationale (and limitations) of selecting the particular animal model should be discussed
- **Clinical Evidence**
  - demonstrates conformity of the device with applicable EP
  - Address elements contained in Clinical Evaluation Report