PREPARING SOFTWARE VALIDATION REPORT

GLOBAL MEDICAL DEVICE CONSULTING

VEE CARE (ASIA) LTD

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

MD 653109

SOFTWARE VALIDATION PROCESS

1. Software Development Planning
2. Software Requirements Specification
3. Software Risk Analysis
4. Software Architecture Design
5. Software Detailed Design
6. Software Implementation & Verification
7. Software Traceability Analysis
8. Software Configuration Management
9. Software Problem Resolution

SOFTWARE VALIDATION REPORT

1. SOFTWARE CLASSIFICATION

1.1 FDA
1.2 EU
1.3 IEC 62304

2. SOFTWARE DEVELOPMENT PLAN

3. SOFTWARE DESCRIPTION

3.1 Intended use
3.2 Hardware Platform
3.3 Operating System
3.4 Software Inputs & Outputs
3.5 Software Functional Characteristics
3.6 User Interface
3.7 Operational Environment

4. SYSTEM AND SOFTWARE ARCHITECTURE DIAGRAM

4.1 Software System Overview
4.2 Operation Flowchart

5. RISK MANAGEMENT FILE

5.1 Risk Estimation
5.2 Risk Acceptance Criteria

6. SOFTWARE REQUIREMENTS SPECIFICATION (SRS)

6.1 Hardware requirements
6.2 Software Programme Language
6.3 Software/Hardware Interface Requirements
6.4 Software Performance and Functional Requirements

7. SOFTWARE DESIGN SPECIFICATION (SDS)

7.1 Hardware Specifications
7.2 Program Specifications
7.3 Interface Specifications
7.4 Performance and Functional Specifications

SOFTWARE VALIDATION REPORT

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