

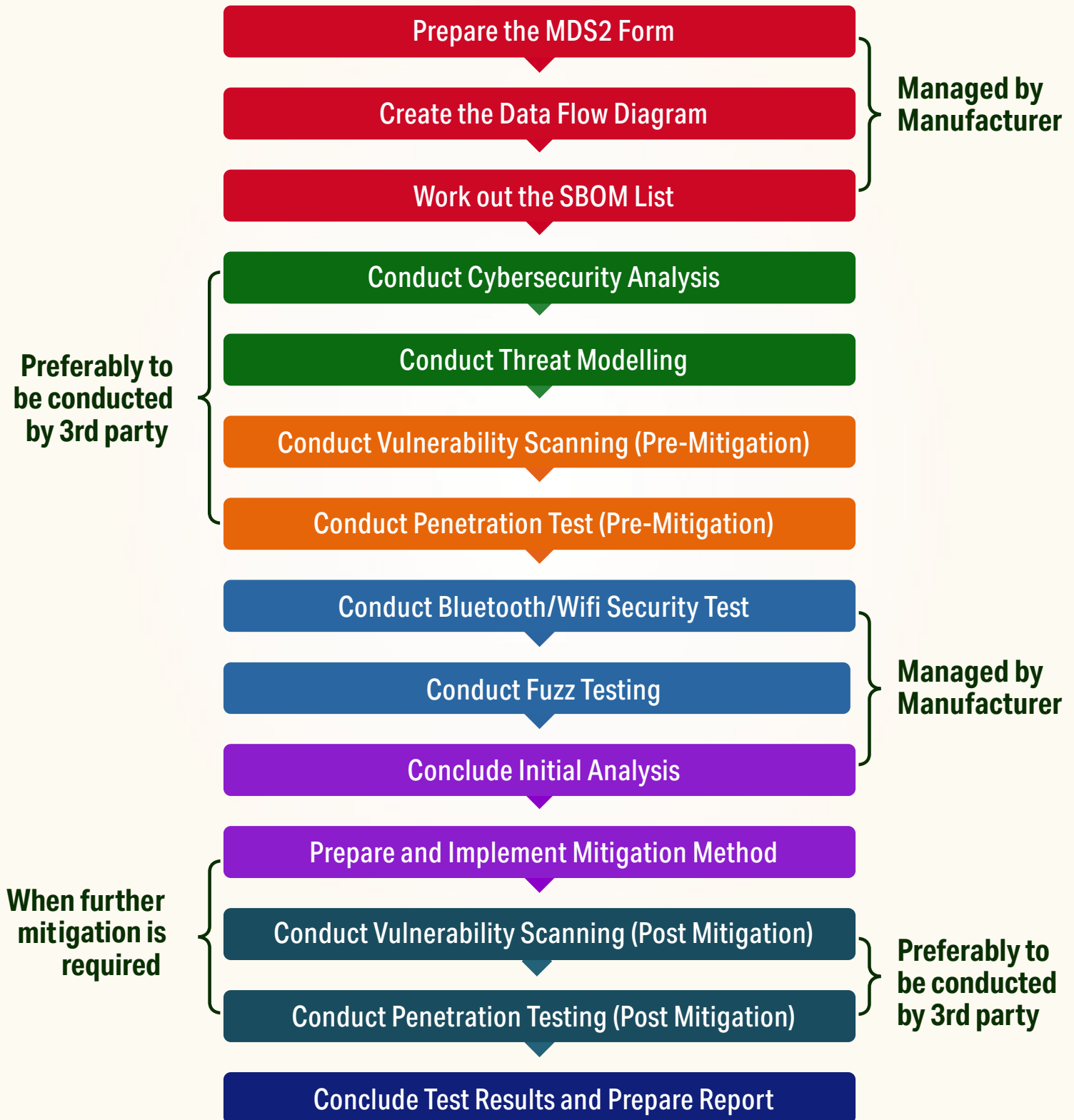
PREPARING CYBERSECURITY REPORT

GLOBAL MEDICAL DEVICE CONSULTING

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PREPARING CYBERSECURITY REPORT

Cybersecurity Report Preparation Process



PREPARING CYBERSECURITY REPORT

Cybersecurity REPORT



1. INTRODUCTION

- 1.1 Document Overview
- 1.2 Evaluation Team
- 1.3 References

2. DEVICE/SYSTEM OVERVIEW

- 2.1 Document Overview
- 2.2 Evaluation Team
- 2.3 References
- 2.4 Software Development Tools
- 2.5 Identification and Classification of Software and Hardware Components

3. CYBERSECURITY RISK MANAGEMENT

- 3.1 Risk Impact Considerations
- 3.2 Risk Management Process Overview

4. CYBERSECURITY RISK ANALYSIS

- 4.1 Asset Identification
- 4.2 Data Flow Diagram (DFD)
- 4.3 Software Bill of Materials (SBOM) and Related Information
- 4.4 Threat Methodology
- 4.5 Threat Identification
- 4.6 Architecture Views
- 4.7 Global System View
- 4.8 Multi-Patient Harm View
- 4.9 Updateability/Patchability View
- 4.10 Security Use Case Views

5. CYBERSECURITY RISK ASSESSMENT

- 5.1 CVSS Table
- 5.2 Risk Evaluation Matrix

6. CYBERSECURITY CONTROL

- 6.1 Security Requirement Specification (SRS)
- 6.2 Security Detail Design (SDD)
- 6.3 Security Verification and Validation (SVV)
- 6.4 Cybersecurity Risk Control Summary

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Cybersecurity REPORT



7. CYBERSECURITY TESTING
7.1 Manual Firmware Security Check Report
7.2 Vulnerability Test
7.2.1 Source Code Analysis
7.2.2 Firmware Source Code Analysis
7.3 Penetration test
8. CYBERSECURITY ASSESSMENT RESULTS SUMMARY
8.1. Cybersecurity Traceability Matrix Table
9. INTEROPERABILITY
9.1 Interoperability Risk Assessment
9.2 Interoperability Verification/Validation
10. CYBERSECURITY LABELING
11. UNSOLVED ANOMALIES ASSESSMENT
12. CYBERSECURITY METRICS
13. CYBERSECURITY POST MARKET CONSIDERATIONS
14. CYBERSECURITY MANAGEMENT PLAN
14.1 Scope
14.2 Workflow

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