Connected Medical Device Risk Analysis Report

1. Device Information

Device Name	
Model/Version	
Manufacturer	
Date of Analysis	
Prepared By	

2. Purpose & Scope

Brief description of the intended use, scope, and boundaries of the risk analysis.

3. System Overview

General overview of system architecture, connectivity, and use cases.

4. Identified Assets

Asset	Description

5. Threats & Vulnerabilities

Threat	Vulnerability

6. Risk Evaluation

Risk ID	Asset	Threat	Impact	Likelihood	Initial Risk Level

7. Existing Controls

Control	Description

8. Residual Risks & Recommendations

Risk ID	Residual Risk Level	Recommendations

9. Approval & Sign-off

Name	Title	Date	Signature