

Medical Device IT Vendor Review Questionnaire

1. Vendor Information

Vendor Name

Contact Person

Email

Phone

Address

2. Product / Service Information

Product / Service Name

Description

Intended Use

Supported Standards (e.g. DICOM, HL7, FHIR)

3. Regulatory & Compliance

Regulatory Approvals / Certifications

GDPR / HIPAA Compliance

Quality Management System in Use

4. Cybersecurity

User Authentication Methods

Data Encryption Methods

Vulnerability Assessment Practices

Incident Response Process

5. Service & Support

Support Channels

Service Level Agreement (SLA)

Maintenance & Update Policy

6. Additional Notes