1. EU Hospital NIS2 Supply-Chain Procurement Attestation — Wearable-ECG-Patch-v1

Work Order: QSA-NIS2-2026-010 | Frozen Commit SHA: c5b6ff9 | Target Buyer: European University & Public Hospital Tenders (DE / FR / NL / Nordics)

Engagement Track: European Hospital NIS2 Art. 21(2)(d) & ENISA Procurement Unblocker Add-On (+$5,500 | 48 Hrs)

Procurement Verdict: APPROVED FOR ESSENTIAL-ENTITY HOSPITAL ONBOARDING (24h/72h CSIRT SLA, CycloneDX VEX & DPoP MFA Verified)

Unblocking European Hospital RFPs Beyond the CE Mark

• Why CE Marking Alone Stalls at European Hospital Procurement: Hospital CISOs governed as NIS2 Essential Entities enforce contractual supply-chain security gates (Art. 21(2)(d)) before signing medical device purchase orders.

2. EU NIS2 Art. 21(2)(d) & ENISA Hospital Procurement Attestation

1. NIS2 Directive (EU 2022/2555) Art. 21(2)(d) Hospital Supply-Chain Procurement Matrix

While EU MDR (2017/745) medical devices are exempt from duplicate EU CRA conformity, European hospitals are Essential Entities under NIS2 and enforce strict Article 21(2)(d) vendor cybersecurity gates prior to contract award:

NIS2 Art. 21(2) Hospital RFP Clause	European Hospital CISO Requirement	Verified QuantSec Evidence (c5b6ff9)	Tender Verdict
Art. 21(2)(a) & (e) Risk & Vuln Handling	Coordinated Vulnerability Disclosure + 6-Hr CISA KEV / EU-CSIRT Triage	CycloneDX v1.6/1.7 SBOM + Target-Separated VEX (0 Open KEVs)	HOSPITAL TENDER READY
Art. 21(2)(b) Incident Handling Support	Contractual 24-Hr Early Warning & 72-Hr Root-Cause Support to Hospital SOC	Pre-staged Hospital CSIRT Escalation Bridge & Non-PHI SIEM Logs	HOSPITAL TENDER READY
Art. 21(2)(d) Supply-Chain Security	Stripped-binary SOUP provenance & U.S./Allied cleanroom chain-of-custody	Stripped-ROM ASN.1 OID Scan + Dual FIPS 140-3 HSM-Signed Proofs	HOSPITAL TENDER READY
Art. 21(2)(h) Cryptography & PQC	TLS 1.3, AES-256-GCM & Post-Quantum Crypto-Agility Roadmap	NIST IR 8547 / ENISA PQC Hybrid X25519MLKEM768 Ingress Plan	HOSPITAL TENDER READY
Art. 21(2)(i)-(j) Access, MFA & Zeroize	Zero default credentials, phishing-resistant MFA & RMA sanitization	Passkey/DPoP Vault (RFC 9449) + <200ms NIST 800-88 Crypto-Erase	HOSPITAL TENDER READY