1. Executive EU CRA (Reg. 2024/2847) & Robotics Attestation — Apex-Sequencer-v2

Work Order: QSA-CRA-2026-006 | Frozen Commit SHA: c5b6ff9 | Target Sector: Commercial IoT, RUO Biotech & Autonomous Robotics

Engagement Track: Standalone Non-Medical EU CRA, EN 18031 & EU Machinery Reg (2023/1230) Sprint ($19.5K-$32.5K | 5-7 Days)

Statutory Gate: EU CRA ARTICLE 14 ENISA 24H/72H REPORTING LIVE (SEPT 11, 2026) — Full CE-Mark Conformity Ready Ahead of Dec 2027 Cutoff

Executive Scope Summary

• Who Needs This Dossier: Manufacturers of non-MDR connected hardware (DNA sequencers, analytical lab instruments, industrial gateways, and autonomous robots) exempt from EU MDR yet strictly subject to EUR 15M / 2.5% global turnover fines under EU CRA.

2. EU CRA Annex I, EN 18031 Wireless & EU 2023/1230 Robotics Matrix

1. EU Cyber Resilience Act (Regulation 2024/2847) Annex I Essential Requirements Matrix

Evaluated for non-MDR connected products with digital elements (RUO biotech/DNA lab instruments, commercial/warehouse robotics, industrial OT gateways, and wellness wearables).

EU CRA Annex I Clause	Statutory Requirement (CE-Mark Gate)	QuantSec Cleanroom Verification Proof	Verdict
Annex I Part I (1)(a)-(b)	Zero Known Exploitable Vulns at Placement & Secure-by-Default	CycloneDX v1.6/1.7 SBOM/VEX (0 Open KEVs) + Zero Default Passwords (CWE-798)	CONFORMANT
Annex I Part I (1)(d)-(f)	Confidentiality & Integrity of Data/Commands + Cryptographic Agility	AES-256-GCM, TLS 1.3 + NIST IR 8547 / FIPS 203-204 PQC Transition Plan	CONFORMANT
Annex I Part I (1)(j)-(l)	Attack Surface Minimization & Exploitation Mitigation	Stripped-ROM OID scan, JTAG/SWD APPROTECT lock & Watchdog DoS recovery	CONFORMANT
Annex I Part II (1)-(8)	Vulnerability Handling, Machine-Readable SBOM & 5-Yr Free Security OTA	Signed MCUboot OTA + ISO/IEC 29147 CVD (security@quantsecadvisory.com)	CONFORMANT

2. Harmonized Wireless (EN 18031) & Autonomous Machinery (EU 2023/1230) Crosswalk

European Harmonized Regime	Applicable Clause	Verified Hardware / Firmware Control	Status
EU RED Delegated Act (EN 18031-1/-2)	Art. 3.3(d) Network Harm & Art. 3.3(e) Privacy	BLE 5.3 LE Secure Connections, replay nonce & RF storm rate-limiting	VERIFIED
EU Machinery Reg (EU 2023/1230)	Annex III §1.1.9 & §1.2.1 Corruption Protection	Hardware safety-circuit isolation (<150ms safe-stop independent of comms MCU)	VERIFIED
Industrial / Lab OT (ISA/IEC 62443-4-2)	Component Security Level SL-2 (CR 1.1 - 7.8)	Authenticated CAN-FD / ROS2 SROS2 / HTTPS actuation & tamper-evident logs	VERIFIED

3. Mandatory EU CRA Art. 14 (24h/72h ENISA SRP) Reporting Protocol

1. Mandatory EU CRA Article 14 ENISA Single Reporting Platform (SRP) Runbook (Live Sept 11, 2026)

Non-compliance with Article 14 reporting or Annex I obligations carries administrative fines up to EUR 15,000,000 or 2.5% of worldwide annual turnover (CRA Art. 64).

Statutory Clock	ENISA SRP / CSIRT Submission Milestone	Required Technical Payload (Pre-Staged by QuantSec)	Owner
<= 24 Hours (Art. 14(2)(a))	Early Warning Notification (Actively Exploited Vuln or Severe Incident)	Affected SKU (Apex-Autonomous-Lab-Sequencer-v2), Frozen SHA (c5b6ff9), Member State distribution list & CISA KEV / CVE flag	OEM PSIRT + QuantSec 6h Watch
<= 72 Hours (Art. 14(2)(b))	Vulnerability / Incident Notification	Root-cause CWE/EMB3D vector, exploitability VEX proof, interim hospital/industrial mitigation & IoCs	QuantSec Cleanroom + OEM Eng
<= 14 Days (Vuln) / 1 Mo (Inc.)	Final Remedial Report (Art. 14(2)(c) / 14(4)(c))	Signed OTA patch SHA-256, updated CycloneDX v1.6/1.7 SBOM/VEX & customer advisory	OEM Release + EU Importer/AR