1. Executive 8-Region IMDRF N60 & IEC 81001-5-1 Attestation — Wearable-ECG-Patch-v1

Work Order: QSA-GLB-2026-004 | Frozen Commit SHA: c5b6ff9 | Parent Proof: 00_FDA_eSTAR_524B_Master_Submission.pdf

Harmonized Core Standards: IMDRF/CYBER WG/N60 & N70 (TPLC), IEC 81001-5-1:2021, ISO 14971:2019, AAMI TIR57 & CycloneDX v1.6/1.7

Commercial Add-On Schedule: Modular Regional Crosswalk Annexes (+$3.5K-$9.5K per market | Zero Re-Testing of Frozen SHA)

Test Once, Submit Globally — 8-Track Free-World Regulatory Architecture

Regional Add-On Module	Statutory Framework	Turnaround & Fee	Local Holder / CSO Scope
Track A1: Health Canada MDL	SOR/98-282 Class III/IV, IMDRF ToC Ch. 3.5 & PIPEDA	24-48 Hrs (+$3,500)	English Accepted (French Lay-IFU)
Track A2: Australia TGA & Swiss	TGA EP 12.1 (FDA COR) + Swissmedic MedDO / July 2026 swissdamed	48 Hrs (+$4,000)	English Tech File (CH-REP UDI Link)
Track A3: ASEAN & LATAM Reliance	Singapore HSA GL-10-R1 (Aug 2026), Mexico COFEPRIS (30d), INVIMA	48 Hrs (+$4,500)	English (HSA) / Spanish IFU (LATAM)
Track B1: UK MHRA & NHS DTAC 2.0	UK MDR + April 2026 NHS DTAC 2.0 Form, PAQ & DCB0129 Safety Case	3 Days (+$5,500)	100% English (Sponsor CSO Sign-Off)
Track B2: Brazil ANVISA & LGPD	ANVISA RDC 657/2022, RDC 751, Guide 38 & IN 290/2024 (FDA/HC EFA)	3 Days (+$6,000)	BRH Translates 14-Pt IFU (Portuguese)
Track B3: Allied GCC (KSA / UAE)	Saudi SFDA (MDS-G38/G37/G030 GHAD), UAE EDE, Qatar, Bahrain, Kuwait	3 Days (+$6,500)	English Tech File (Arabic IFU by AR)
Track C: Japan PMDA / MHLW	Essential Principles Art. 12(3) & JIS T 81001-5-1:2023 + Offline Ports	4 Days (+$8,500)	MAH Translates Summary & JPCERT CVD
Track D: South Korea MFDS	DMPA + MFDS 35-Item Checklist (0995-06 Nov 2026: SI-05 & SI-07)	5 Days (+$9,500)	KLH Translates SI-07 Catalog (Korean)

SOVEREIGNTY, EXPORT-CONTROL & TRANSLATION BOUNDARY: QuantSec Advisory (E-Comm Systems Inc.) executes all binary extraction, adversarial testing, and regulatory traceability strictly inside U.S.-Sovereign AWS us-east-2 cleanrooms (EAR ECCN 5A002 / ITAR 22 CFR 120.62 safe) and delivers English-language technical dossiers. Consumer/lay-user labeling translation (Canadian French, Swiss National Languages, Spanish, Portuguese, Arabic, Japanese, Korean) and national portal submissions remain strictly the responsibility of Sponsor's local Registration Holder, Clinical Safety Officer (UK CSO), or Authorized Representative (MDL / CH-REP / UKRP / SFDA-EDE AR / BRH / MAH / KLH). PRC / China NMPA in-country testing and all OFAC-embargoed jurisdictions (including Iran) are strictly excluded.

2. Canada (Health Canada SOR/98-282 & IMDRF ToC) Annex

1. Health Canada Premarket Cybersecurity Guidance & IMDRF ToC (SOR/98-282) Crosswalk

Health Canada MDL Requirement	Statutory / IMDRF ToC Node	Mapped QuantSec Master Proof	Filing Status
Secure Design & Risk Management	SOR/98-282 Sec. 10-20 / IMDRF ToC Ch. 3.5	00_FDA_eSTAR_524B_Master_Submission.pdf Sec. 1-2 (AAMI TIR57 + ISO 14971)	DIRECT ENGLISH MDL READY
Verification & Adversarial Testing	Health Canada Premarket Cyber Guidance	Sec. 3.1 Unaltered 9x-GIAC Pen-Test + BLE/API Fuzzing	DIRECT ENGLISH MDL READY
SBOM, CBOM & TPLC Patch Plan	IMDRF N60 / N73 Software Transparency	CycloneDX v1.6/1.7 JSON (001_SBOM_CBOM_CycloneDX.zip) + 5-Yr EOS	CONFORMANT
Mandatory Problem Reporting & PIPEDA	SOR/98-282 Sec. 59-61.1 & Federal PIPEDA	10-Day (Serious) / 30-Day Incident Escalation + Zero On-Patch PHI	READY (FRENCH IFU BY SPONSOR)

3. Australia TGA & Switzerland Swissmedic (MedDO / swissdamed) Annex

1. Australia TGA (Essential Principle 12.1) & Switzerland Swissmedic (MedDO / swissdamed) Crosswalk

Authority & Instrument	Governing 2026 Pathway / Deadline	Mapped QuantSec Cleanroom Proof	Filing Status
Australia TGA (ARTG Inclusion)	Essential Principle 12.1 + TGA Cyber Guidance (FDA COR Reliance)	00_FDA_eSTAR_524B_Master_Submission.pdf + CycloneDX v1.6/1.7 SBOM/VEX	100% ENGLISH READY
Switzerland Swissmedic (MedDO SR 812.213)	EU MDR GSPR 17.2 / US FDA Recognition Alignment + CH-REP	Master Binder Sec. 9 GSPR Crosswalk + Same-SHA (c5b6ff9)	ENGLISH TECH FILE ACCEPTED
Swiss swissdamed UDI & Vigilance Gate	Mandatory July 1, 2026 UDI Module (Dec 31, 2026 Cutoff / Apr 2027 Importer Link)	Locked Software Version (c5b6ff9) + Immediate Incident Escalation to CH-REP	CH-REP PORTAL READY

2. Swissmedic 2026 Transition & TGA Abbreviated Reliance Notes

• Swissmedic swissdamed Mandatory Trigger: Per Swissmedic's July 1, 2026 Product Module mandate (grace period ending Dec 31, 2026; immediate registration required upon any postmarket FSCA/vigilance event), this annex locks exact UDI software build c5b6ff9 for Sponsor's CH-REP.

• Australia TGA Comparable Overseas Regulator (COR): Reuses US FDA §524B clearance + English IMDRF N60 dossier with zero re-testing.

4. UK MHRA, NHS England DTAC 2.0 (Apr 2026) & DCB0129 Safety Bridge

1. United Kingdom MHRA, NHS England DTAC 2.0 (April 2026 Form) & DCB0129 Clinical Safety Pack

Reflects the updated NHS DTAC 2.0 form mandatory from April 6, 2026 (replacing legacy DTAC forms) alongside NHS Pre-Acquisition Questionnaire (PAQ) hardware triggers and DCB0129 Clinical Safety Case verification.

UK / NHS Procurement Gate	Governing 2026 Standard	Mapped QuantSec Technical Evidence	NHS Trust Readiness
UK MHRA Registration (GB & NI)	UK MDR 2002 (Indefinite CE Recognition) + UKRP Part 4A Vigilance	Dual-Harmonized FDA/EU Master Binder (c5b6ff9) + UKRP Vigilance Routing	UKRP FILING READY
NHS DTAC 2.0 (Sec. C Cyber + PAQ)	April 6, 2026 DTAC Form + DSIT/NCSC Software Security Code of Practice	9x-GIAC Pen-Test (Zero High/Crit), MFA/DPoP AuthZ, SBOM/VEX & Hardware PAQ	NHS TRUST PROCUREMENT READY
NHS Data Security (DSPT / UK GDPR)	NHS Data Security & Protection Toolkit + Cyber Essentials Plus Equiv.	Encrypted AWS Transit/Rest, Zero On-Patch PHI & 14-Pt IFU Controls	DSPT EVIDENCE MAPPED
NHS DCB0129 Hazard Log Bridge	DCB0129 Clause 6.3.2 / 6.3.3 Security-to-Clinical Control Verification	Bidirectional T-01..T-08 -> HAZ-01..08 (<500ms Alarm Proof) for CSO Sign-Off	READY FOR CSO APPROVAL

2. Clinical Safety Officer (CSO) & DTAC 2.0 Boundary

• DTAC 2.0 Hardware vs. Companion Split: Per Feb/April 2026 NHS England rules, companion mobile/cloud software (TB-3/TB-4) maps directly into DTAC 2.0, while embedded wearable patch hardware (TB-1/TB-2) attaches via the NHS Pre-Acquisition Questionnaire (PAQ).

• DCB0129 Clinical Governance Boundary: QuantSec provides verified likelihood/control-effectiveness proofs (VER-PEN-01..VER-LOG-08); final Clinical Safety Case Report sign-off remains strictly with Sponsor's qualified Clinical Safety Officer (CSO).

5. Singapore HSA (GL-10-R1) & LATAM Reliance Annex

1. Singapore HSA (GL-10-R1 Aug 2026) & ASEAN / LATAM Reliance Mapping

Jurisdiction & Instrument	Governing Standard / Pathway	Mapped FDA §524B Master Proof	Build Parity & Filing Status
Singapore HSA (GL-10-R1 Aug 2026)	IMDRF N60/N70 TPLC, ISO 14971 & IEC 81001-5-1	00_FDA_eSTAR_524B_Master_Submission.pdf Sec. 2-7 + CycloneDX v1.6/1.7 SBOM/CBOM	DIRECT ENGLISH DOSSIER READY
Malaysia MDA / ASEAN Reliance	ASEAN CSDT + HSA Abbreviated Reliance Route	Same-SHA (c5b6ff9) Threat Model, VEX & 9x-GIAC Pen-Test	RELIANCE ELIGIBLE
Mexico COFEPRIS (Equivalence)	30-Business-Day IMDRF / FDA Clearance Reliance	FDA §524B Clearance + Same-Binary SHA Attestation (c5b6ff9)	SPANISH IFU BY LOCAL HOLDER
Colombia INVIMA / Rest of LATAM	Direct FDA / CE Technical Evidence Recognition	Master Binder Sec. 1-10 + Signed SHA256SUMS.p7s	SPANISH IFU BY LOCAL HOLDER

6. Brazil ANVISA RDC 657 / IN 290 (FDA Reliance) & LGPD Annex

1. Brazil ANVISA RDC 657/2022 (SaMD), RDC 751/2022 & IN 290/2024 Crosswalk

ANVISA Requirement	Statutory Clause	QuantSec Technical Evidence	Adjudication
Equivalent Foreign Authority Proof	IN 290/2024 + RDC 751/2022	US FDA §524B Master Binder (c5b6ff9) + Dual-HSM Seal	ELIGIBLE (AREE RELIANCE)
SaMD & Connected Architecture	RDC 657/2022 Art. 14 / Guide 38	Trust Boundary DFD (TB-1..TB-4), BLE 5.3 Nonce & BOLA API Proof	VERIFIED
Cloud Residency & LGPD Safeguards	Lei 13.709/2018 (LGPD Art. 46)	TLS 1.3 API Gateway -> Encrypted Tenant Partition (LGPD Art. 33/46 Standard Clauses); zero plaintext CPF/PHI on patch	DOCUMENTED
Portuguese IFU Security Summary	RDC 751/2022 Labeling	14-Point IFU Security Summary isolated in English for BRH translation	READY FOR BRH TRANSLATION

7. Allied GCC: Saudi SFDA (MDS-G38/G030), UAE EDE & Gulf Reliance Annex

1. Allied GCC States — Saudi SFDA (GHAD), UAE EDE & Gulf Reference Reliance

GCC Authority & Portal	Governing Cyber / MDMA Rule	Mapped QuantSec Cleanroom Proof	2026 Filing Posture
Saudi Arabia SFDA (GHAD MDMA)	MDS-REQ 1, MDS-G38 (Premarket) & MDS-G37 (Postmarket)	Full Standalone Cyber Dossier + SBOM/CBOM (c5b6ff9) — satisfies MDS-G030 (Sept 2026) 510(k) full-file rule	ENGLISH GHAD FILE READY
Saudi NCMDR & PDPL Hospital Gate	MDS-REQ 11 Vigilance + Saudi PDPL / NCA ECC	2-Workday (Public Threat) / 10-Workday NCMDR Escalation + Zero-PHI Logs	SAUDI AR HANDOFF READY
UAE Emirates Drug Est. (EDE)	2026 MOHAP->EDE Transfer + ADHICS v2 / NABIDH	US FDA / CE Reference Dossier + MDS2/SBOM Pack for Abu Dhabi/Dubai HDOs	ENGLISH EDE PORTAL READY
Bahrain NHRA / Qatar MOPH / Kuwait & Oman	GCC Reference Country Reliance (FDA / CE / HC)	Same-SHA (c5b6ff9) Equivalency Certificate + Dual-HSM Signed Master PDF	FAST-TRACK RELIANCE READY

8. Japan PMDA JIS T 81001-5-1:2023 & Offline Port Audit

1. Japan PMDA / MHLW Essential Principles Art. 12(3) & JIS T 81001-5-1:2023 Crosswalk

JIS T 81001-5-1:2023 Clause	PMDA / MHLW Review Focus	Mapped QuantSec Cleanroom Proof	Status
Clause 5.1 - 5.3 (Security Context & Risk)	Bidirectional ISO 14971 / JIS T 14971 Safety Bridge	Sec. 2 TIR57 Matrix + Sec. 3.4 IEC 60601-1-8 (<500ms Alarm)	CONFORMANT
Clause 5.4 - 5.5 (Architecture & Updatability)	Hardware RoT, MCUboot Signing & Anti-Rollback	CTRL-AUTH-01 (ECDSA-P256 + LMS Roadmap) & PID-13	CONFORMANT
Clause 5.6 (SBOM & SOUP Governance)	Machine-Readable SBOM/CBOM + CISA KEV / JVN Triage	CycloneDX v1.6/1.7 JSON (001_SBOM_CBOM_CycloneDX.zip)	CONFORMANT
Clause 5.7 (Verification & Pen Testing)	Independent Adversarial Fuzzing, BLE & API BOLA	Sec. 3.1 Unaltered 9x-GIAC Pen-Test (8.5 Manual Eng Hrs)	CONFORMANT
Clause 8 / PSEHB Notification (CVD & EOS)	Japanese MAH Vulnerability Intake (JPCERT/CC) & EOS	5-Yr EOS Commitment + MAH CVD Escalation Bridge (ISO 29147)	MAH HANDOFF READY

2. Mandatory PMDA Offline, Servicing & Physical Debug Port Assessment

• Physical JTAG / SWD / UART Servicing Interfaces (PID-11 / TID-101): Hardware readback protection (APPROTECT / RDP Level 2) verified active on production silicon; authenticated per-unit challenge required before factory RMA unlock.

• Japanese MAH CVD Routing: Reports to security@quantsecadvisory.com (48-hr SLA) mirror to Sponsor's Japanese MAH for PMDA / JPCERT/CC coordination.

9. South Korea MFDS DMPA 35-Item (SI-05 / SI-07) Matrix

1. South Korea MFDS Digital Medical Products Act (DMPA) & 35-Item Checklist (0995-06 Nov 2026)

Part A: SI-05 Explicit Six-Vector External Input Architectural Justification

MFDS SI-05 Input Vector	Device Applicability	Engineering Proof / Architectural N/A Justification
1. Wireless RF (BLE / Wi-Fi / Cellular)	APPLICABLE	BLE 5.3 LE Secure Connections + monotonic replay nonce + PDU fuzzing (VER-RF-03, VER-FUZZ-04).
2. Network / Cloud API Interfaces	APPLICABLE	TLS 1.3 + SPKI pinning + server-enforced BOLA/IDOR tenant ACLs (VER-BOLA-07, <=15 RPS verified).
3. Companion Mobile / Host OS IPC	APPLICABLE	Unexported Android Intents / iOS URL scheme bounds + Build A MASVS RASP (VER-MASVS-05).
4. Removable Media & USB Mass Storage	NOT APPLICABLE (N/A)	Architectural Proof: Sealed wearable patch contains zero USB host/device controller, SD slot, or mass-storage stack in Zephyr prj.conf.
5. Web Browser / SQL Database Engine	NOT APPLICABLE (N/A)	Architectural Proof: Embedded MCU runs bare-metal/RTOS C firmware with zero HTTP server, DOM parser, or SQL engine (CWE-89/CWE-79 structurally impossible).
6. Physical Debug / Clinical Console Ports	APPLICABLE (LOCKED)	Production eFuse/APPROTECT disables SWD/UART (PID-11); zero external keypad or unauthenticated serial console exposed.

Part B: SI-07 Complete User-Facing Security Error & Anomaly Message Catalog (KLH Translation Source)

Event Code	Trigger Condition	Exact English UI / Companion Alert String (For KLH Korean Translation)	Safe-State Action
SEC-ERR-01	BLE Pairing MITM / Auth Failure	Security Alert: Patch authentication failed. Move to a private area and re-pair device.	Drops BLE link; maintains local ECG piezo alarm.
SEC-ERR-02	Invalid OTA Firmware Signature	Update Blocked: Firmware integrity check failed (ECDSA/LMS). Running verified clinical image.	Rejects bank swap; logs non-PHI HMAC event.
SEC-ERR-03	Compromised / Rooted Handset	Environment Warning: Untrusted mobile OS detected. Clinical telemetry upload paused.	Blocks cloud token; local patch alarm stays active.
SEC-ERR-04	Cloud Session / Token Expired	Session Expired: Please re-authenticate via biometric or passkey to view ECG trends.	Locks companion screen after 5-min idle (Sec. VI.B #7).
SEC-ERR-05	RF Interference / GATT Flood	Connection Degraded: High wireless interference detected; local on-patch monitoring active.	Watchdog <150ms recovery; <=500ms alarm preserved.