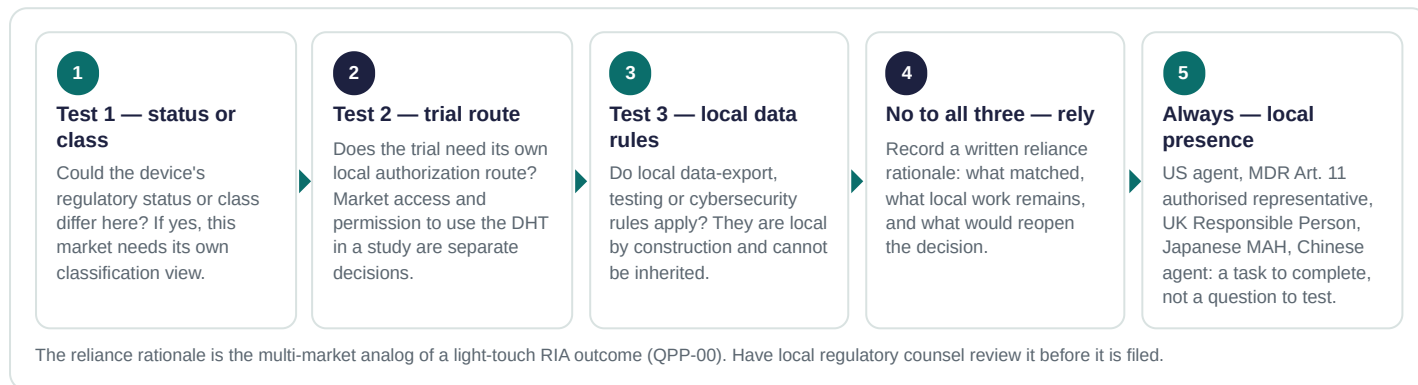


A DHT accepted in one major market is not, by that fact, deployable in the others: lead-market acceptance is evidence, not a passport.

Three questions decide whether a market needs its own assessment; one yes means local work, no to all three means the work already done can be relied on — if the reliance is written down and dated. **Reconcile the differences market by market; do not wait for a harmonization that does not exist.**

THE PICTURE

Three questions decide whether a market needs its own assessment; in-country representation is not one of them



QOINTA'S POSITION Only the conduct and evidence layer carries across all five markets

What carries is the conduct layer, nothing below it

ICH E6(R3) incl. Annex 2, the IMDRF software risk logic and fitness-for-purpose evidence travel. Classification, trial authorization, registration and data export do not.

Five markets, five authorities — not one of them EMA

FDA; notified bodies and national competent authorities under the MDR with Member States authorizing the trial; MHLW with PMDA; NMPA; MHRA. Bar GB's time-limited CE acceptance, a lead-market clearance binds none.

Status follows function — per market

A symptom-tracking app can be class IIa under MDR Annex VIII Rule 11 in the EU and a lower-risk digital health function elsewhere. Role and function are assessed locally.

Divergence is dynamic; reconciliation is revisited, not done once

Great Britain consults on indefinite CE recognition, the EU AI Act timeline moved in July 2026, Japan extends its SaMD program and China rebuilt its GCP framework in 2026.

SIX STEPS, FROM SHARED GROUND TO RE-CONFIRMATION ON CHANGE

- 1 Anchor on the shared requirements** — ICH E6(R3) including Annex 2, the IMDRF software risk logic and fitness-for-purpose evidence.
- 2 Locate the local differences** — device classification, trial authorization, registration, data export and local testing.
- 3 Test materiality** — decide which differences actually affect this deployment rather than cataloging all of them.
- 4 Decide on local assessment** by applying the three tests; where none bites, write and date the reliance rationale.
- 5 Satisfy the standing requirement** for in-country representation in every market — it never discriminates between them.
- 6 Re-confirm on change** — when a market is added, a regime moves, or the device's role shifts in one territory.

3

tests decide whether a market needs its own assessment; one yes means local work

5

markets, five different authorities deciding classification, trial route and registration

15 Jan 2027

ICH E6(R3) Annex 2 takes effect in the EU (Step 4 reached 3 June 2026; still draft at FDA)

30 Jun 2028 / 2030

CE marks accepted for placing a device on the Great Britain market, subject to a UK Responsible Person

Read with care. Market statements are current at 1 September 2026. The China row is qointa's understanding pending confirmation by China-qualified counsel; AI and data positions move fastest and must be re-confirmed before each market entry.

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-02 Data Residency and Cross-Border Transfer · QPP-03 Economic-Operator Roles · QPP-05 Cybersecurity · QPP-16 PCCP · QPP-22 Continuous Monitoring and Consent



Summary of QPP-23 1.0 — the full paper, with sources and figures, is published at qointa.com.

ICH E6(R3) incl. Annex 2 · IMDRF software risk logic · FDA DHT guidance s.III · MDR Annex VIII Rule 11 and Art. 11 · CTR 536/2014 · 21 CFR 807.40(b) · Regulation (EU) 2026/1744 (AI Act) · PMD Act · State Council Order No. 739 · PIPL · SI 2025/538
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