

Labelling, UDI and traceability attach to the regulated article — the software, the supplied unit or the sensor — **never to the phone, tablet or gateway that carries it.**

Two threshold questions decide whether any duty arises: is the app a medical device, and is it investigational? **The sponsor's three moves: name the article, settle its status, and hold the version trail of which build reached whom** — the GCP control that device-law traceability, stopping at the economic operator, does not supply.

THE PICTURE Each article carries its own duties; the platform is never the article

ARTICLE Medical device software (app) Annex I s.23 label; in-app IFU permitted. System-level UDI; new UDI-DI or UDI-PI per change (Annex VI C 6.5).	ARTICLE Sponsor-supplied marketed device IFU for each market; relabelling or translation triggers Art. 16. Manufacturer's UDI, registered.	ARTICLE Connected sensor or wearable Manufacturer's label, IFU and UDI if a marketed device; none for a consumer wearable that is not a device.	PLATFORM Phone, tablet or cellular gateway Not the article: no label, no UDI. Documented as model and OS/firmware version; serial-tracked if provisioned.
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An investigational device carries no UDI (MDR Art. 27(1); 21 CFR 801.30(a)(6)); it is labelled 'exclusively for clinical investigation' (Annex I 23.2(q)) or with the 21 CFR 812.5(a) caution statement.

QOINTA'S POSITION 'You can't assign a UDI to a phone' is true — and beside the point

Two threshold questions decide what each article carries Software that only stores, transmits or displays data is not a device (MDCG 2019-11 Rev. 1), so most eCOA / ePRO apps carry no labelling or UDI duty. An investigational device has no UDI.	BYOD makes identification harder, not exempt With participant-owned hardware there is nothing to label, so identification moves onto the software, its distribution and its version — which build, pushed through which mechanism, to whom.	Labelling is market-specific Language (MDR Art. 10(11)), mandatory content (Annex I s.23; 21 CFR Part 801) and acceptable form differ by jurisdiction. A single global package rarely suffices.	Device-law traceability stops at the economic operator Art. 25 reaches operators and health institutions, not participants. The participant-level version trail is qointa's recommended GCP control, not a UDI duty.
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FIVE STEPS, FROM NAMING THE ARTICLE TO RE-CONFIRMING ON CHANGE

- 1 Settle the article and its status** — app, supplied unit or connected sensor; a device at all; investigational or marketed.
- 2 Apply labelling and IFU per market** — MDR Annex I s.23 in each Member State's language; 21 CFR Part 801 in the US; in-app IFU for software.
- 3 Assign and register the UDI** for a marketed device before placing on the market (Arts 27, 29; EUDAMED / GUDID); none if investigational.
- 4 Trace the chain** to the operator or site that received the device (Art. 25), and add the participant-level version trail as a GCP control.
- 5 Re-confirm on every change:** new UDI-DI for algorithm or data-interpretation changes, new UDI-PI for minor revisions; re-check per market.

28 May 2026 EUDAMED actor and UDI/device registration mandatory (Decision (EU) 2025/2371)	12 months to register devices already on the market after the OJ notice — late Nov 2026
25 years trial retention period (CTR Art. 58) for the version-trail log qointa recommends	30 June 2028 CE marking accepted in Great Britain (MDR); no GB UDI requirement yet in force

Read with care. Illustrative only — what counts as the regulated article is a matter for structured assessment. EUDAMED vigilance modules, the GB reform and the Commission's December 2025 MDR revision proposal (COM(2025) 1023) are in progress.

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