

Your device keeps its own obligations; the combination decides the data — and reliability is **won or lost at the boundary** with the hub.

Pairing with a phone, tablet or gateway transfers none of your classification, performance envelope or measurement claim. It puts a seam between your device and the hub, where pairing, transformation and timestamping happen.

Document the interface, the performance envelope and the timing model, and pre-answer the bundling question.

THE PICTURE Four facts decide whether your readings survive the crossing

DEVICE STATUS

Your device keeps its own classification

Pairing does not move it. Where the combination has an intended purpose of its own, its class is assessed on its own footing.

INTEROPERABILITY

The combination, not your device, determines the data

Whether it is also an MDR system or procedure pack is a separate, conditional question under Art. 22.

BOUNDARY

The seam preserves or degrades your data

Pairing, transformation and timestamping happen there. If the hub timestamps, time integrity sits with the hub, not you.

ENDPOINT VALIDATION

Bench performance is not trial performance

A measurement claim has to hold in the trial population — the point of the sponsor's verification and validation work.

Pairing does not create a system or procedure pack — placing the combination on the market does. The EU computerised-systems guideline requires date and time to be captured automatically and beyond the user's reach; someone must evidence it, and it is not automatically you.

QOINTA'S POSITION Three arrangements quietly move the risk onto you

An undocumented link to the hub costs your integrator

A standards-based profile — ISO/IEEE 11073, e.g. 11073-20601:2022 — is cheaper to evidence than a proprietary link, which can be validated but at a cost that lands downstream.

Hub timestamping moves time integrity off your device

Where the phone or gateway stamps the reading, the automatic-capture requirement must be evidenced by whoever controls the hub — decide and declare which it is.

Bundling can make someone the producer of a system or procedure pack

Under MDR Art. 22 the duty follows whoever combines the parts to place them on the market; EUDAMED actor registration has been mandatory for such producers since 28 May 2026.

SIX DISCLOSURES TURN THE BOUNDARY FROM A LIABILITY INTO A SELLING POINT

- 1 Publish a standards-based interface** and an interface document a trial team can read and rely on.
- 2 State your performance envelope** — range, accuracy and the conditions under which the claim holds.
- 3 Own the timing question** — decide and declare whether your device or the hub timestamps readings.
- 4 Bring real-population evidence**, not just bench data, for the measure you claim.
- 5 Pre-answer the bundling question** — know whether a partnership makes you, or your customer, the Art. 22 producer.
- 6 Name the transformations** — any scaling, filtering or algorithm applied before data leaves your device.

Read with care. Use outside a CE-marked intended purpose, or of a device not CE-marked at all, triggers the clinical-investigation route (MDR Arts 62, 74, 82; FDA IDE under 21 CFR Part 812) — a separate question this edition does not cover. Not legal advice.

READ NEXT

QPP-00 Regulatory Impact Assessment (s.12) · QPP-01 Endpoint Validation · QPP-03 Economic-Operator Roles · QPP-14 Interoperability

