

Your Device, and the System It Joins

A companion reading from the wearable / biosensor manufacturer seat — your own obligations, and the system the bridge creates

Prepared for	Wearable, biosensor and connected-medical-device manufacturers, and the trial teams integrating them.
Subject	Why a connected device carries its own classification and performance obligations, and how the bridge to the phone or gateway brings it into a system.
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Executive summary

Your device keeps its own obligations; the combination decides the data. A connected device — a continuous glucose monitor (CGM), an ECG patch, a smart inhaler, a wearable — carries its own classification, performance envelope and measurement claim, and pairing it with a phone, tablet or gateway does not transfer them. What pairing does is put a seam between your device and the hub, and the seam decides whether the reading that reaches the trial record is the reading your device took.

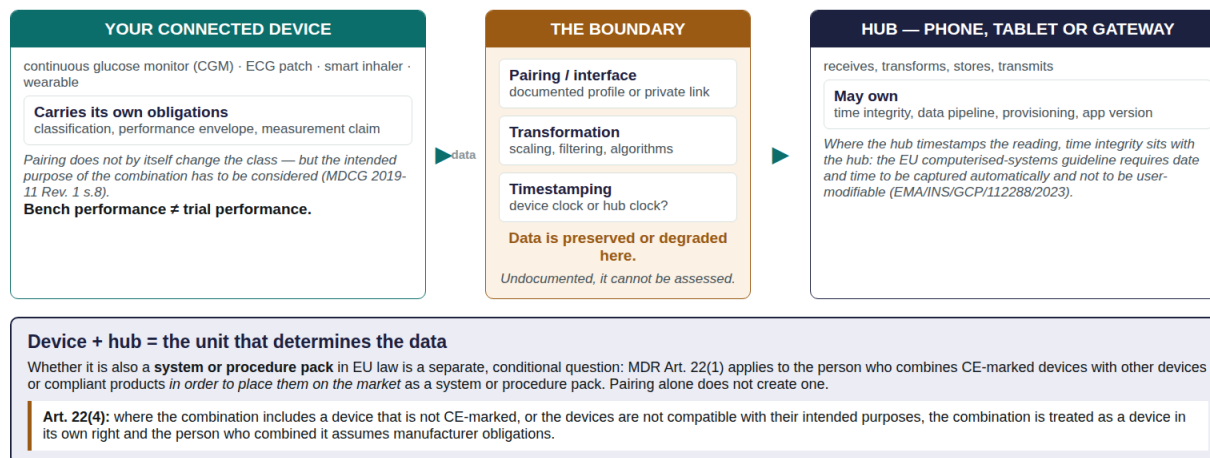
Data reliability is won or lost at the boundary. Pairing, transformation and timestamping all happen there. Where the hub — the phone or the gateway — timestamps the reading, time integrity sits with the hub, and the EU computerized-systems guideline requires date and time to be captured automatically and to be beyond the user's reach — a requirement someone must evidence, and it is not automatically you.

Document the interface, the performance envelope and the timing model, and pre-answer the bundling question. Those four things make the combined system assessable and make yours the device an integrator can defend. The bundling question is the one most makers leave open: under MDR Art. 22 it is the person who combines the parts *in order to place them on the market* as a system or procedure pack who picks up producer duties — and where the combination includes a device that is not CE-marked, or the devices are not compatible with their intended purposes, that person assumes full manufacturer obligations.¹

¹ EMA, "Guideline on computerised systems and electronic data in clinical trials" (EMA/INS/GCP/112288/2023, adopted 7 March 2023), s.6.1.3 (direct capture) and Annex 4; see also 21 CFR 11.10(e) (secure, computer-generated, time-stamped audit trails). https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf

Data reliability is won or lost at the boundary, not inside your device

Pairing, transformation and timestamping all happen at the seam between your device and the hub — phone, tablet or gateway.



Document the interface, the performance envelope and the timing model, and the combined system becomes assessable — yours is then the easy device to integrate.

Illustrative. Whether Art. 22 applies to a given arrangement is a fact-specific assessment.

Figure 1 — Data reliability is won or lost at the boundary, not inside your device.

1. You keep your obligations; the bridge to the hub adds a second set

This edition reads the series from the connected-device manufacturer's seat. Your device is regulated on its own terms: qualification and classification follow the intended purpose you declare, not the hardware it happens to talk to. Pairing does not move that — but where the combination itself has a new intended purpose, the class of that combination has to be considered on its own footing.²

It is written for connected-device product and regulatory teams and for the trial teams integrating them. Where a device is used outside its CE-marked intended purpose, or is not CE-marked at all, the clinical-investigation route (MDR Arts 62, 74 and 82, or an FDA investigational device exemption under 21 CFR Part 812) is a separate question this edition does not cover — raise it early.

² Regulation (EU) 2017/745 (MDR), Art. 2(10) ("procedure pack": products "packaged together and placed on the market with the purpose of being used for a specific medical purpose"), Art. 2(11) ("system"), Art. 22(1)–(2) (statement of mutual compatibility, information supplied, internal monitoring and validation) and Art. 22(4) (non-CE-marked devices or incompatible combinations are treated as a device in their own right and the person combining assumes manufacturer obligations). Consolidated text verified at <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02017R0745-20250110>

How this fits the full framework

This edition is keyed to Section 12 of the Regulatory Impact Assessment (QPP-00). It summarizes positions set out in full, with sources, in the numbered papers — the ties most relevant to a connected-device maker are:

- **QPP-00 — Regulatory Impact Assessment (RIA).** Where your device's status and obligations are assessed rather than assumed.
- **QPP-01 — Endpoint Validation.** Whether your measure is fit for purpose in the trial population, not only on the bench.
- **QPP-03 — Economic-Operator Roles.** How bundling and assembly move manufacturer, importer and system or procedure pack producer duties between parties.
- **QPP-14 — Interoperability.** Why the combination, not your device alone, is what the trial has to assess.

Regulatory basis

The sources behind this edition. The detail, and the rest of the citations, are in the numbered papers.

- **MDR (EU) 2017/745** Art. 2(10)–(11), Art. 16(1), Art. 22(1)–(4) — systems and procedure packs: who combines, for what purpose, and when the combination is treated as a device in its own right.
- **MDCG 2023-4** (October 2023), *MDSW – Hardware combinations* — the three options for software intended to run with hardware, and where responsibility for the hardware in combined use falls.
- **MDCG 2019-11 Rev. 1** (June 2025), ss.3.1 and 8 — intended purpose governs qualification and classification; the intended purpose of a new combination must be considered when determining its class.
- **EMA/INS/GCP/112288/2023** (adopted 7 March 2023), s.6.1.3 and Annex 4 — device metadata with directly captured data; automatic, non-modifiable date and time.
- **FDA, Digital Health Technologies for Remote Data Acquisition in Clinical Investigations** (final guidance, December 2023), s.III — verification and validation for the proposed use, whatever the device status.
- **Commission Implementing Decision (EU) 2025/2371** — EUDAMED actor registration mandatory from 28 May 2026 for manufacturers, importers and system or procedure pack producers.
- **ISO/IEEE 11073** family (e.g. 11073-20601:2022, personal health device communication).

Everything in this edition that is not attributed to a source above is qointa's professional assessment.

2. Four facts decide whether your readings survive the crossing

- **Your device keeps its own classification.** Pairing does not move it. Where the combination has an intended purpose of its own, the class of that combination is assessed on its own terms.
- **The combination, not your device alone, determines the data.** Whether it is also an MDR system or procedure pack is a separate, conditional question (Figure 2).
- **The boundary preserves or degrades your data.** Pairing, transformation and timestamping happen at the seam.

- **Bench performance is not trial performance.** A measurement claim has to hold in the trial population, not on the bench — the point of the verification and validation work the sponsor must complete.³

3. Your device sits inside four perimeters it does not control

Your device sits inside four perimeters it does not fully control. Each maps to a paper in the series, and each turns on a decision on your product roadmap.

Perimeter / topic	What it means for you	Paper	Why it matters to your product roadmap
Device status	Your device's own classification and performance obligations.	QPP-00	Class and claims drive your evidence plan and time-to-market — settle them early.
Interoperability	The combination determines the data; whether it is also an MDR system or procedure pack depends on Art. 22.	QPP-14	Designing a clean, standards-based interface makes you the partner integrators choose.
Endpoint validation	Your measure must be fit for purpose in this population.	QPP-01	Real-population evidence is what converts a sensor into an accepted endpoint.
Economic operator	Bundling can shift operator duties to whoever assembles the system.	QPP-03	Know whether a partnership makes you — or your customer — the producer of a system or procedure pack.

Pairing does not create a system or procedure pack — placing the combination on the market does

Three questions from MDR Art. 22 decide who, if anyone, picks up producer or manufacturer duties when your device is bundled with a phone or gateway.

QUESTION 1 Is the combination placed on the market as a system or procedure pack? Art. 22(1) bites on the person who combines devices <i>in order to place them on the market</i> as a system or pack. A sponsor pairing a CE-marked device with a phone or gateway for its own trial is not doing that.	QUESTION 2 Is every device in it CE-marked, and are they compatible with their intended purposes? Art. 22(1) also covers non-device products that comply with the legislation applying to them. Art. 22(2) requires a statement: mutual compatibility verified, information supplied, internal monitoring and validation applied.	QUESTION 3 Is the pack sterilized, or does it fail either test above? Art. 22(4) is the sharp edge: a non-CE-marked device in the pack, or an incompatible combination, and the pack is treated as a device in its own right.
Neither → no Art. 22 duties Your device keeps its own classification, claims and performance obligations. The combination still decides the data quality — that is the boundary question in Figure 1.	Yes to 1 and 2 → system / procedure pack producer The person combining draws up the Art. 22(2) statement, and registers as a system or procedure pack producer in EUDAMED (actor registration mandatory since 28 May 2026).	Art. 22(4) → treated as a device The person who combined it assumes manufacturer obligations for the combination: conformity assessment, technical documentation, vigilance.

Pre-answer this before a partnership is signed: whether it is you or your customer who picks up the duty is a commercial term, not an afterthought.

Illustrative. Whether Art. 22 applies to a given arrangement is a fact-specific assessment; see QPP-03 — Economic-Operator Roles.

Figure 2 — Pairing does not create a system or procedure pack — placing the combination on the market does.

³ MDCG 2019-11 Rev. 1 (June 2025), s.3.1 (the operating system, server or environment does not affect qualification; the intended purpose declared by the software manufacturer governs qualification and classification) and s.8 (the intended purpose and functionality of a new combination must be considered when determining its class).

https://health.ec.europa.eu/document/download/b45335c5-1679-4c71-a91c-fc7a4d37f12b_en?filename=mdcg_2019_11_en.pdf

4. Three arrangements quietly move the risk onto you

- **An undocumented link to the hub.** A documented, standards-based profile — the ISO/IEEE 11073 family, for example 11073-20601:2022 for personal health devices — is cheaper to evidence than a proprietary link. A proprietary link can be verified and validated; it just costs more, and the cost lands on your integrator.
- The hub, not your device, timestamping readings. Time integrity then sits with the hub, not you.
- **Bundling that makes 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 — and EUDAMED actor registration has been mandatory for manufacturers, importers and system or procedure pack producers since 28 May 2026 (Figure 2).⁴

5. Six disclosures turn the boundary from a liability into a selling point

Six disclosures turn the boundary from a liability into a selling point. The checklist below is the same list in short form.

- **Publish a standards-based interface** and an interface document a trial team can read and rely on.
- **State your performance envelope** — range, accuracy and the conditions under which the claim holds.
- **Own the timing question** — decide and declare whether your device or the hub timestamps readings.
- **Bring real-population evidence** — not just bench data — for the measure you claim.
- **Pre-answer the bundling question** — know whether a given partnership makes you, or your customer, the producer of a system or procedure pack under MDR Art. 22 (QPP-03 — Economic-Operator Roles).
- **Name the transformations** — any scaling, filtering or algorithm applied before the data leaves your device.

⁴ FDA, “Digital Health Technologies for Remote Data Acquisition in Clinical Investigations” (final guidance, December 2023), s.III: verification and validation of the DHT for the proposed use, regardless of its device status.

Device-maker checklist — trial-ready connected devices

Six things that make your device the easy one to integrate defensibly:

- **Document the interface.** A documented, standards-based profile (ISO/IEEE 11073 family) is cheaper to evidence than a proprietary link.
- **State the performance envelope.** Operating range, accuracy and the conditions under which the claim holds.
- **Declare the timing model.** Whether the device or the hub timestamps readings — and where time integrity sits.
- **Name the transformations.** Any scaling, filtering or algorithm applied before the data leaves you.
- **Show real-population evidence.** Performance in the intended population, not only bench data.
- **Flag the bundling question.** Be clear who becomes the producer of a system or procedure pack when your device is combined with a hub, and who assumes manufacturer obligations if Art. 22(4) applies.

6. How qointa can help

qointa writes the boundary documentation an integrator can rely on — the interface document, the performance envelope, the timing model and the transformation list — and runs the MDR Art. 22 analysis on a proposed bundling arrangement before it becomes a contract term. We also advise the sponsors on the other side of that negotiation, so the questions your device will be asked are ones we have written.

Scope and status

This is a companion edition summarizing qointa's position-paper series from one stakeholder's seat, keyed to Section 12 of the Regulatory Impact Assessment (QPP-00). It summarizes positions set out in full, with sources, in QPP-01 — Endpoint Validation, QPP-03 — Economic-Operator Roles and QPP-14 — Interoperability. It is not legal advice; any specific position should be confirmed with qualified regulatory counsel.