

When a hub pairs with a sensor, wearable, spirometer or CGM, the combined system — not the sensor alone — is the unit of assessment, and someone must answer for it.

"The phone just relays the data" holds only where the hub forwards a sealed reading unchanged; a hub that pairs, transforms, timestamps or derives is part of the instrument. **Scope the combination in the RIA, test the five boundary questions, validate the interface on a documented standard, and assign the system responsibility.**

THE PICTURE

Five questions at the device-to-device boundary decide whether the endpoint survives the crossing

At the boundary	The question	Evidence needed
Pairing / identity	Is the right sensor bound to the right participant and session?	Attribution is ALCOA++ (EMA guideline s.4.5); validate the pairing-to-identity binding
Transformation	Does the hub reformat, calibrate or derive — validated?	If it derives the clinical value the app is MDSW (MDCG 2019-11 Rev. 1); validate the transformation
Timestamping	Whose clock stamps the reading — sensor's or hub's?	Automatic timestamps from a trusted, traceable time source (EMA guideline s.5.5)
Completeness	Are dropped or buffered readings detected, or do gaps pass silently?	Gap detection and buffered-data handling inside the validated transfer (s.6.1.2)
Standards	Documented, interoperable interface — or an undocumented private link?	ISO/IEEE 11073, ITU-T H.810 Continua or HL7 FHIR by reference; a proprietary link specified and validated in full

Illustrative case: a CGM-paired study buffered readings on the phone whenever Bluetooth dropped and back-filled them with no gap flag; an audit found mis-timed, interpolated values. The sensor was sound; the boundary was not.

QOINTA'S POSITION Three questions decide which regime governs the hub-plus-sensor system

Does the hub app have a medical purpose of its own?

If it derives the clinical value it is software as a medical device in its own right, on whatever platform it runs (MDCG 2019-11 Rev. 1), and carries its own obligations.

Are CE-marked devices placed on the market together?

MDR Art. 22 applies: the assembler issues the statement; the phone or gateway sits in only as a justified "other product" (Art. 22(1)(c)); exceeding intended purpose makes a device (22(4)).

Is the sensor investigational?

MDR Arts 62–82 and Annex XV govern and the sponsor holds the obligations; a marketed device modified for the trial shifts the manufacturer's duties under Art. 16(1)(b)–(c).

On every route, the boundary is a validated interface

EMA/INS/GCP/112288/2023 s.6.1.2 requires validated data transfer; FDA's DHT guidance requires the DHT verified and validated for the investigation regardless of device status.

FIVE ACTIONS THAT MAKE THE BOUNDARY EVIDENCED

- 1 Assess the combination as the regulatory unit** and scope it in the RIA whenever the hub pairs with and reads from another device.
- 2 Validate the transformation or derivation** against the endpoint and treat the hub as part of the device when it processes the signal.
- 3 Use a trusted, traceable time source** on the hub and evidence its integrity when the hub, not the sensor, timestamps the reading.
- 4 Assign the system responsibility** on the applicable route — Art. 22 assembler, MDSW manufacturer or sponsor — and record it in the register.
- 5 Move to a documented, standards-based interface** where one exists; otherwise specify and validate the proprietary link in full.

Read with care. FDA has no equivalent of the MDR Art. 22 system / procedure pack, so multi-jurisdiction trials must classify the system per market. That multi-device endpoints are increasing is qointa's assessment; no count is cited.

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-01 Endpoint Validation · QPP-03 Economic-Operator Roles · QPP-08 Trigger Register



Summary of QPP-14 1.0 — the full paper, with sources and figures, is published at qointa.com.

MDCG 2019-11 Rev. 1 · MDR Art. 2(25)–(26), 16(1)(b)–(c), 22, 62–82, Annex I, XV · EMA/INS/GCP/112288/2023 s.4.5, 5.5, 6.1.2 · FDA DHT guidance (Dec 2023) · FDA interoperability guidance · 21 CFR Part 11 · ISO/IEEE 11073

© qointa 2026 – Public – Uncontrolled when printed · Not legal advice; this summary does not classify any device.

qointa · DHT governance for clinical trials
sales@qointa.com · qointa.com