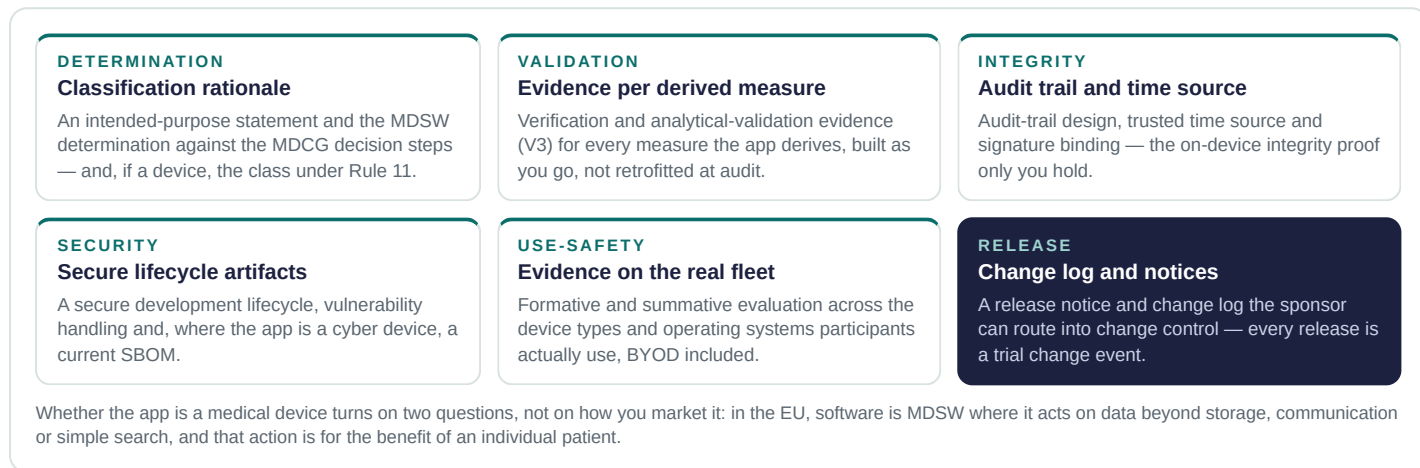


# Settle two questions **before a sponsor asks**: is the app a medical device, and can you hand over the evidence package?

"We're just the software provider" rarely describes where an eCOA / ePRO vendor lands. Whatever the device answer, you own evidence the sponsor cannot produce for you, and each release is a change event in a live trial. **Build the package as you go: a vendor that can hand it over is qualified in weeks, not quarters.**

## THE PICTURE

**Your build and release choices are the sponsor's evidence — and the sponsor cannot produce them for you**



## QOINTA'S POSITION Four facts place you inside the regulated unit, not beside it

|                                                                                                                                                                                                      |                                                                                                                                                                                               |                                                                                                                                                                                                        |                                                                                                                                                                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Your app can be the device</b><br>MDSW is placed on the market in its own right; the phone or tablet it runs on does not change that. Where it is placed on the market, you are its manufacturer. | <b>You own the evidence others rely on</b><br>Validation, audit trail, change control and security of the app are yours, because only you hold them. The sponsor cannot produce them for you. | <b>You are also overseen</b><br>The sponsor retains ultimate responsibility for your output under ICH E6(R3) and has to qualify and monitor you — you are almost always a processor, not a controller. | <b>Your releases are the trial's change events</b><br>An update can move the app across a perimeter mid-study. Marketing does not decide device status: a "wellness" feature that scores or alerts for an individual can be MDSW. |
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**SIX RECORDS MAKE YOU EASY TO QUALIFY**

- Determine the app's status early** — hold an intended-purpose statement and an MDSW determination against the MDCG decision steps.
- Build the validation package as you go** — analytical-validation evidence for each derived measure, not retrofitted at audit.
- Make integrity and security demonstrable** — audit trail, trusted time source, signature binding, secure lifecycle, SBOM for a cyber device.
- Evaluate use-safety on the real fleet** — formative and summative, across the device types and operating systems participants use.
- Treat every release as a change event** — issue a notice and change log the sponsor can route into change control.
- Hold the instrument licences and migration evidence** — copyright position per COA instrument and equivalence to the version replaced.

**2**

questions to settle before a sponsor asks: is the app a device, and can you hand over the evidence

**7**

regulatory perimeters apply to the app; you hold the evidence for most of them

**3**

blind spots that turn up at vendor qualification: wellness framing, reference-device validation, unapproved sub-processors

**6**

records that turn a hidden obligation into an evidence package

**Read with care.** Companion edition keyed to Section 12 of QPP-00. In qointa's assessment a connectivity carrier is usually not your sub-processor but a controller for its own traffic data; the hosting and analytics chain is, and needs the controller's authorization under GDPR Art. 28(2) and (4).

**READ NEXT**

QPP-00 Regulatory Impact Assessment · QPP-01 Endpoint Validation · QPP-02 Data Residency · QPP-03 Economic-Operator Roles · QPP-04 AI/ML Overlay · QPP-05 Cybersecurity · QPP-07 Change Control · QPP-09 Human Factors · QPP-10 Data Integrity · QPP-12 Vendor Qualification and Oversight



**Summary of S04 1.0** — the full paper, with sources and figures, is published at qointa.com.

ICH E6(R3) · MDCG decision steps and MDR Rule 11 · GDPR Art. 28(2) and (4) · IEC 62366-1:2015+A1:2020 · IEC 62304 · IEC 81001-5-1:2021 · FD&C Act s.524B · FDA general wellness and device software function policies

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