

Ask one question before you quote a study: **is anything in the kit a medical device?** If not, no EU operator role attaches to you; if so, your own operations attach duties.

Sourcing, configuring, kitting and recovering devices are the triggers — and no contract assigns the roles they attach. **Record the answer either way: determine the operator role per study before sourcing, document provisioning against intended purpose, and evidence sanitization to a named level.**

THE PICTURE Each step can attach a duty — once there is a device in the kit

SOURCING

Third-country sourcing makes you the importer

Placing a device from a third country on the Union market: MDR Art. 2(33), duties in Art. 13. Shipping ordinary phones or gateways does not.

CONFIGURING

Changing intended purpose gives you manufacturer obligations

Art. 16(1)(b)–(c). Imaging and locking down a handset does not by itself move it out of general purpose — the record evidences the sponsor's intended purpose.

BUNDLING

Placing a sensor kit on the market makes you a pack producer

Art. 22(1), where the combination is placed on the market; a pack with a non-CE-marked device is itself a device (Art. 22(4)). EUDAMED registration since 28 May 2026.

RECOVERING

Sanitization and custody are yours whatever the answer

Purge level under NIST SP 800-88 Rev. 2 with verification, unbroken chain of custody, WEEE and battery duties on disposal.

Each limb presupposes a device: none is triggered by locking down a plain phone. Radio-equipment, product-safety, WEEE, battery and lithium-transport duties apply to every phone you ship regardless.

QOINTA'S POSITION Two perimeters turn on device status; two apply to every shipment

Operator roles follow what you do, not the contract

Importer (Art. 13), distributor (Art. 14), manufacturer (Art. 16(1)) or pack producer (Art. 22) attach from sourcing and kitting where a device is involved — the duty most often unassigned.

Configuration records evidence the sponsor's intended purpose

Imaging, lock-down and kitting are documented against the intended use the sponsor has set — evidenced, not assumed.

A sanitization clause must name the level, not the method

"Not a factory reset" prohibits the recognized method on a managed iOS fleet. Specify Purge under NIST SP 800-88 Rev. 2, the method appropriate to the media, and the verification.

Devices in transit and at recovery still hold personal data

GDPR Arts 28, 30, 32 and 33 apply: hold the Art. 30 record, Art. 28 processor terms, Art. 32 measures and an Art. 33 path for a device lost in transit.

FOUR ACTIONS TURN AN INHERITED DUTY INTO A DATED RECORD — BEFORE SOURCING, NOT AFTER THE AUDIT

- 1 Answer the threshold question and record your operator role** per study — including "none" — dated before sourcing.
- 2 Document configuration against intended use** so imaging, lock-down and kitting are evidenced, not assumed.
- 3 Evidence sanitization and custody to the end:** Purge level specified, method fit for the media, verification and custody log on file.
- 4 Get the duties named in contract** so no role is inherited silently from how you operate.

Read with care. Contract clauses in the edition are drafting points, not legal drafting: qointa is not a law firm. That imaging and lock-down do not remove a handset from general purpose is qointa's assessment — no MDCG guidance says it does.

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-03 Economic-Operator Roles · QPP-13 Decommissioning · QPP-02 Data Residency and Cross-Border Transfer · QPP-18 Vigilance and PMS



Summary of S05 1.0 — the full paper, with sources and figures, is published at qointa.com.

Regulation (EU) 2017/745 (MDR) Arts 2(33), 13, 14, 16(1)(b)–(c), 22, 13(8), 14(5) · EUDAMED actor registration · NIST SP 800-88

Rev. 2 · GDPR Arts 28, 30, 32, 33 · WEEE, battery and lithium-transport rules

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