

The Provisioning Chain's Inherited Duties

A companion reading from the logistics / provisioning vendor seat — how sourcing and configuration draw operator and end-of-life duties

Prepared for	Logistics, provisioning and device-fulfillment vendors, and the sponsors that contract them.
Subject	How provisioning, sourcing and recovery draw economic-operator and end-of-lifecycle duties — often unassigned.
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Executive summary

Ask one question before you quote a study: is anything in the kit a medical device? If nothing is, no EU medical-device operator role attaches to you, and a general-purpose smartphone that neither is, nor hosts, a medical device does not make its shipper an MDR importer.¹ If something is, the duties below attach to the operations you already perform — and, because no contract names them, they are usually unassigned until an audit finds them.

Where there is a device, the actions you already perform are the trigger. Sourcing from a third country makes you the importer (Art. 13). Changing the intended purpose of a device, or modifying it so compliance may be affected, gives you manufacturer obligations (Art. 16(1)(b)–(c)). Kitting a phone or a cellular gateway with a sensor and placing the combination on the market makes you the producer of a system or procedure pack (Art. 22). Each limb presupposes a device: none of them is triggered by locking down a plain phone.

Record the answer either way. Determine the operator role per study before sourcing, document the provisioning and kitting you perform against the intended purpose the sponsor has set, and evidence recovery to a named sanitization level with verification. For most shipments the honest assessment returns minimal medical-device controls — and a dated record saying so is what makes a provisioning vendor a defensible partner. Radio-equipment, product-safety, WEEE, battery and lithium-transport duties apply to the phones you ship whatever the medical-device answer.²

¹ Regulation (EU) 2017/745 (MDR): Art. 2(33) defines the importer as a person established in the Union that places a device from a third country on the Union market; importer duties are in Art. 13 and distributor duties in Art. 14. Art. 16(1) applies manufacturer obligations to a distributor, importer or other person who (a) makes a device available under its own name, (b) changes the intended purpose of a device already placed on the market or put into service, or (c) modifies such a device so that compliance may be affected — each limb presupposes a device. Art. 22(1)–(2) covers the person who combines CE-marked devices with other devices or compliant products in order to place them on the market as a system or procedure pack, and Art. 22(4) treats a pack containing a non-CE-marked device, or an incompatible combination, as a device in its own right. Consolidated text verified at <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02017R0745-20250110>

² Radio Equipment Directive 2014/53/EU; General Product Safety Regulation (EU) 2023/988; WEEE Directive 2012/19/EU; Batteries Regulation (EU) 2023/1542; lithium-battery transport under UN 38.3 and the IATA Dangerous Goods Regulations.

Each step you perform can attach a duty no contract names — but only once there is a device in the kit

The EU operator duties below turn on medical-device law. Shipping ordinary phones or gateways attaches other law instead, not this.

The threshold question: is anything in the kit a medical device, or does the kit make one? A general-purpose smartphone that neither is, nor hosts, a medical device does not make its shipper an MDR importer (QPP-03 — Economic-Operator Roles). Radio-equipment, general product safety, WEEE, battery and lithium-transport duties apply either way.

1 · Sourcing bring devices in from a third country	2 · Kitting and configuration image, lock down, bundle phone or gateway with sensor	3 · Deployment ship and hand devices to sites and participants	4 · Recovery and end of life collect, sanitize, dispose
DUTY IF A DEVICE Importer A person established in the Union placing a device from a third country on the Union market — MDR Art. 2(33), duties in Art. 13; distributors, Art. 14.	DUTY IF A DEVICE Manufacturer, or pack producer Art. 16(1)(b)–(c): changing the intended purpose of a device already placed on the market, or modifying it so compliance may be affected. Art. 22(1)(4) where the kit is placed on the market as a system or procedure pack.	DUTY ALWAYS Processor of personal data GDPR Art. 28 (processor terms and sub-processors), Art. 30 (record of processing), Art. 32 (security), Art. 33 (breach notification for a device lost in transit).	DUTY ALWAYS Sanitization and custody Purge-level sanitization with verification — NIST SP 800-88 Rev. 2 (September 2025). WEEE and battery duties on disposal.
⚠ Risk point A role no contract assigns is still a role you hold.	⚠ Risk point Both provisions presuppose a device; neither is triggered by locking down a plain phone.	⚠ Risk point A device in transit still holds identifiers and participant data.	⚠ Risk point "Not a factory reset" is the wrong test: on a managed iOS fleet the cryptographic erase is the recognized method. Name the level and verify it.

Determine and record the operator role per study before sourcing — and record the conclusion when it is "none".

Illustrative. Which duties attach to a given operation is a fact-specific assessment with the sponsor and qualified regulatory counsel.

Figure 1 — Each step you perform can attach a duty no contract names — but only once there is a device in the kit.

1. The threshold question comes before every duty in this edition

This edition reads the series from the logistics and provisioning vendor's seat. Everything in it is conditional on the threshold question (Figure 2): EU medical-device law reaches a logistics operation only where a device is in the kit, or the kit creates one. Where it does, the route by which devices are sourced and the configuration you perform decide which operator role you hold.

It is written for provisioning and fulfillment teams and the sponsors that contract them. Figure 1 sets out the four operations and the duties each can attach; Figure 2 sets out the threshold question and the law that applies whatever its answer.

One question decides whether medical-device duties attach at all

For most shipments the honest answer returns minimal medical-device controls — and that conclusion is worth recording.

Always, whatever the answer — the law that governs shipping phones and gateways Radio Equipment Directive 2014/53/EU · General Product Safety Regulation (EU) 2023/988 · WEEE Directive 2012/19/EU · Batteries Regulation (EU) 2023/1542 · lithium-battery transport (UN 38.3 / IATA DGR) · GDPR Arts 28, 30, 32 and 33 where the devices carry participant data · ICH E6(R3) s.3.6 where you are the sponsor's service provider.	
Is anything in the kit a medical device — or does the kit create one? MDR Art. 2(1): qualification follows the manufacturer's intended purpose.	
No — no MDR operator role A general-purpose smartphone that neither is, nor hosts, a medical device does not make its shipper an MDR importer. - Art. 13 importer duties and Art. 14 distributor duties presuppose a device placed on the Union market - Art. 16(1) presupposes a device already placed on the market or put into service - Record the assessment and its date: "no obligation" is a conclusion, not an assumption	Yes — the operator duties attach Establish which role you hold for each device route, per study, before sourcing. Importer — MDR Art. 2(33), duties Art. 13; distributor — Art. 14 Manufacturer obligations — Art. 16(1)(b)–(c), where you change the intended purpose or modify the device so compliance may be affected System or procedure pack producer — Art. 22(1)–(2); Art. 22(4) where the pack contains a non-CE-marked device or an incompatible combination - EUDAMED actor registration, mandatory since 28 May 2026
qointa's assessment: imaging and lock-down do not, by themselves, move a handset out of "general purpose". No MDCG guidance says they do. What they can do is evidence the intended purpose the sponsor has given the configuration — which is why the configuration record belongs in the Regulatory Impact Assessment.	

Ask the threshold question once per study, record the answer, and the rest of the analysis is proportionate to it.

Illustrative. Qualification and operator-role questions are fact-specific and should be confirmed with qualified regulatory counsel.

Figure 2 — One question decides whether medical-device duties attach at all.

2. Four operations can attach a duty — each one only where there is a device

- **Sourcing a device can make you its importer.** Placing a medical device from a third country on the Union market makes you the importer under MDR Art. 2(33), with the duties in Art. 13. Shipping ordinary phones or cellular gateways does not.
- **Configuring a device can give you manufacturer obligations.** Art. 16(1)(b)–(c) applies where you change the intended purpose of a device already placed on the market, or modify it so that compliance may be affected. In qointa's assessment, imaging and locking down a handset does not by itself move it out of "general purpose": no MDCG guidance says it does, and qualification follows the manufacturer's intended purpose. What the configuration record does is evidence the intended purpose the sponsor has given the setup.
- **Bundling can make you the producer of a system or procedure pack.** Art. 22(1) covers the person who combines CE-marked devices with other devices or compliant products in order to place them on the market as a system or pack; Art. 22(4) treats a pack containing a non-CE-marked device, or an incompatible combination, as a device in its own right. Since 28 May 2026 such producers must be registered as actors in EUDAMED.³
- **Recovery and disposal are yours to evidence whatever the device answer.** Sanitize to a named level with verification, keep an unbroken chain of custody, and meet the WEEE and battery duties on disposal.

3. Two perimeters turn on device status; two apply to every shipment

The first two rows below attach only where there is a device in the kit; the last two apply to every shipment. The third column names the vendor action and the evidence that discharges it. The economic-operator row is flagged because, in qointa's experience, it is the duty most often left unassigned.

Perimeter / topic	What it means for you	Vendor action / evidence	Series paper
Economic operator	Importer (Art. 13), distributor (Art. 14), manufacturer (Art. 16(1)) or system / procedure pack producer (Art. 22) duties from sourcing and kitting — where a device is involved.	Determine and record your operator role per study before sourcing.	QPP-03
Configuration	Configuration records evidence the intended purpose the sponsor has set for the setup.	Document imaging, lock-down and kitting against the intended use.	QPP-00
Decommissioning	Secure wipe, data remanence and chain of custody at recovery.	Evidence Purge-level sanitization with verification, per NIST SP 800-88 Rev. 2, and an unbroken custody log. ⁴	QPP-13

³ Commission Implementing Decision (EU) 2025/2371: the first four EUDAMED modules, including actor registration, are mandatory from 28 May 2026, with transitional catch-up periods.

⁴ NIST Special Publication 800-88 Rev. 2, "Guidelines for Media Sanitization" (final, 26 September 2025), superseding Rev. 1 of December 2014. Verified at <https://csrc.nist.gov/pubs/sp/800/88/r2/final>. The method that reaches a given level is device-specific: on a managed iOS fleet the built-in cryptographic erase is the recognized method, so "not a factory reset" is the wrong test — name the level and verify it.

Perimeter / topic	What it means for you	Vendor action / evidence	Series paper
Data protection and privacy	Devices in transit and at recovery still hold personal data — GDPR Arts 28, 30, 32 and 33.	Hold the Art. 30 record of processing, the Art. 28 processor terms and a custody-linked asset register.	QPP-02

4. Three habits leave a duty unowned until an audit finds it

- **Roles no contract assigns.** An operator role you hold under the MDR is not created or removed by the contract; it follows what you do.
- **A sanitization clause written against the method instead of the level.** "Not a factory reset" prohibits the recognized method on a managed iOS fleet. Specify the level — Purge under NIST SP 800-88 Rev. 2 — and the verification.
- **No chain of custody to the end.** Recovered devices carry identifiers and residual data until cleared.

5. Six records name and discharge the duties your operations attach

Six records name and discharge the duties your operations attach — including the record that says none attaches.

Checklist item	Evidence that it is done
Threshold question answered and operator role determined per study, before sourcing.	Dated assessment of device status and of the importer, distributor, manufacturer or pack-producer role — including a recorded "none".
Configuration documented against intended use.	Imaging, lock-down and kitting records on file.
Bundling assessed against MDR Art. 22 where a phone or gateway is kitted with a device.	System assessment where a phone or gateway is kitted with a sensor.
Sanitization specified by level, not by method.	Purge level per NIST SP 800-88 Rev. 2, with the method used and the verification recorded.
Chain of custody unbroken to clearance.	Custody log from recovery through wipe / disposal.
GDPR duties covered in transit and at recovery.	Art. 30 record, Art. 28 processor terms, Art. 32 measures and an Art. 33 path for a device lost in transit.

Contract clause recommendations (illustrative)

Drafting points, not legal drafting: qointa is not a law firm, and these are illustrative formulations for your counsel to settle. Their purpose is that no duty is left unassigned.

- **Operator role:** "The parties record, before sourcing and for each device route, whether any product in the kit is a medical device and, if so, which party holds importer, distributor, manufacturer or system / procedure pack producer duties under Regulation (EU) 2017/745."
- **Configuration scope:** "The vendor documents provisioning, lock-down and kitting against the

intended use and provides it on request."

- **End of life:** *"Devices are sanitized to the Purge level of NIST SP 800-88 Rev. 2 by a method appropriate to the media, with the method and its verification recorded, under an unbroken chain of custody to clearance."*
- **Data protection:** *"The vendor maintains the record of processing, processor terms and security measures required by Articles 30, 28 and 32 GDPR for personal data held on devices in transit and at recovery, and notifies the controller without undue delay of any loss under Article 33."*

6. This edition condenses five papers of the series

How this edition fits the qointa series

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:

- **QPP-00 — Regulatory Impact Assessment (RIA).** Where the threshold question is asked and the configuration record kept, per setup and before controls are fixed.
- **QPP-03 — Economic-Operator Roles.** Which role sourcing and kitting attach — and the threshold below which none does.
- **QPP-13 — Decommissioning.** Recovery, sanitization and chain of custody are yours to evidence.
- **QPP-02 — Data Residency and Cross-Border Transfer.** Devices in transit and at recovery still hold personal data.
- **QPP-18 — Vigilance and PMS.** Where a recovered device reveals a fault, importers and distributors must forward complaints and suspected incidents to the manufacturer immediately (MDR Arts 13(8) and 14(5)).

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(1) (qualification follows intended purpose), Art. 2(33) and Art. 13 (importer), Art. 14 (distributor), Art. 16(1)(b)–(c) (manufacturer obligations — each limb presupposes a device), Art. 22(1)–(4) (systems and procedure packs), Arts 13(8) and 14(5) (forwarding complaints and suspected incidents).
- **Commission Implementing Decision (EU) 2025/2371** — EUDAMED actor registration mandatory from 28 May 2026 for manufacturers, importers and system or procedure pack producers.
- **GDPR:** Art. 28 (processors and sub-processors), Art. 30 (record of processing), Art. 32 (security of processing), Art. 33 (breach notification).
- **NIST SP 800-88 Rev. 2**, *Guidelines for Media Sanitization* (final, 26 September 2025), superseding Rev. 1.
- **Product law that applies to the phones whatever the device answer:** Radio Equipment Directive 2014/53/EU; General Product Safety Regulation (EU) 2023/988; WEEE Directive 2012/19/EU; Batteries Regulation (EU) 2023/1542; lithium-battery transport under UN 38.3 and the IATA Dangerous Goods Regulations.
- **ICH E6(R3)**, Annex 1 s.3.6 — service-provider agreements and sponsor oversight.

This edition addresses EU law. A global provisioning operation meets the UK, Swiss and US regimes as well; they are outside its scope. The proposition that provisioning and lock-down move a handset

out of "general purpose" is **qointa's assessment** and is not attributed to any MDCG guidance. Everything else not attributed to a source above is qointa's professional assessment.

7. Record the role before sourcing, not after the audit

Four actions turn an inherited duty into a dated record. None of them costs more than the assessment itself; all of them cost less than finding the duty during an audit.

- **Answer the threshold question and determine your operator role per study** so the conclusion — including "none" — is recorded before sourcing, not inferred later.
- **Document configuration against intended use** so imaging, lock-down and kitting are evidenced, not assumed.
- **Evidence sanitization and custody to the end** so the level is specified, the method is appropriate to the media, and the verification is recorded.
- **Get the duties named in contract** so no role is inherited silently from how you operate.

Example handling statement

A framing a provisioning vendor can record and stand behind — usable only where each sentence is true of the operation, because an auditor will test it against the evidence:

"For each study we record, before sourcing, whether any product in the kit is a medical device and which operator role we hold if it is. We document the provisioning and kitting we perform against the intended purpose the sponsor has set. We handle recovery under an unbroken chain of custody, sanitizing to the Purge level of NIST SP 800-88 Rev. 2 with the method and verification recorded. Personal data held on devices in transit and at recovery is covered by our Article 30 record, processor terms and security measures."

8. How qointa can help

qointa answers the threshold question with provisioning vendors and their sponsors, records the operator role per study and per device route, and builds the configuration, custody and sanitization evidence that discharges it. We also draft the schedule your counsel turns into contract wording, so no duty is left unassigned between sponsor, CRO and provisioning vendor.

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-03 — Economic-Operator Roles, QPP-13 — Decommissioning and QPP-02 — Data Residency and Cross-Border Transfer. It is not legal advice and qointa is not a law firm; any specific position, and any contract wording, should be settled with qualified regulatory counsel.