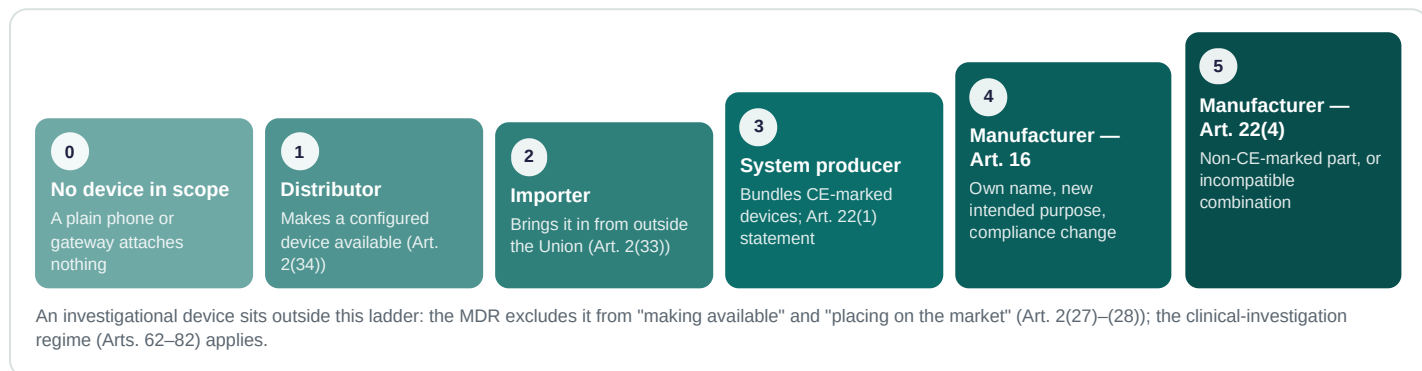


Economic-operator roles attach to what a party does with a medical device, not to its job title — and in a trial they are inherited by operation of law.

Importing a CE-marked device makes you its importer; distributing it, a distributor; bundling it, the system producer; supplying it under your own name or modifying it, the manufacturer (Article 16). **Map the roles on the RIA scoping decision and name a legal entity for each in the contracts before any device moves.**

THE PICTURE Roles attach to conduct and escalate to manufacturer at two points



QOINTA'S POSITION Four positions that separate a role map from a job-title list

"We only ship phones" is true until a device enters the kit

A vendor that imports, locks down, images or bundles devices with a sensor may already carry importer, distributor or system-producer duties — provided a device is in scope at all.

Duties attach to a device, not hardware — settle scope first

MDCG 2019-11 Rev. 1 and MDCG 2023-4 decide whether a device is in scope. A CE-marked device used off-purpose as a data tool is not automatically an MDR clinical investigation (Art. 2(45)).

Routine logistics choices map onto importer and distributor

Provisioning, cross-border import, direct-to-participant shipment and leasing each attach a role. The customs importer of record and the MDR importer are different concepts — name both.

The recurring failure is that nobody assigns the roles

In qointa's experience the allocation is absent from sponsor–vendor contracts at trial start, so an FSMA, recall or EUDAMED check reveals roles that were inherited, never allocated.

SIX DEPLOYMENT FACTS, EACH SETTLED BY A CONTRACT CLAUSE AT THE START

- 1 **Name the placing-on-market party** for provisioned devices; assign importer and distributor duties in the provisioning SOW.
- 2 **Designate an importer of record** and capture conformity-verification and traceability obligations for imported devices.
- 3 **Name both the MDR importer and the customs importer** for direct-to-participant shipments; require accurate customs declarations.
- 4 **Assess every modification against Article 16**; if triggered, allocate manufacturer duties and QMS coverage.
- 5 **Allocate the Article 22 statement** to a named producer; record the phone or gateway as an 'other product' under Art. 22(1)(c).
- 6 **Decide the route — Article 62, 74 or 82 — in the RIA** for off-purpose use, and assign a re-issue owner who documents the data-wipe.

5

MDR roles: manufacturer, authorised rep, importer, distributor, system producer

2

defined points where duties escalate to manufacturer: Art. 16 and Art. 22(4)

28 May 2026

EUDAMED actor registration mandatory (Art. 31; Decision (EU) 2025/2371)

2 Feb 2026

US 21 CFR Part 820 became the QMSR, incorporating ISO 13485:2016

Read with care. Lessor-as-distributor, OS imaging of a plain conduit and MDM enrollment are qointa's assessments, not settled guidance. COM(2025) 1023, the proposed MDR/IVDR revision, is a proposal, not law — check its treatment of Article 16.

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-07 Change Control · QPP-08 Trigger Register · QPP-12 Vendor Qualification · QPP-13 Decommissioning · QPP-19 Labelling and UDI · QPP-23



Summary of QPP-03 1.0 — the full paper, with sources and figures, is published at qointa.com.

EU MDR Arts. 2, 10–14, 16, 22, 31, 62–82, Annex XV · MDCG 2021-27 · MDCG 2019-11 Rev. 1 · MDCG 2023-4 · MDCG 2021-23 · MDCG 2021-26 · Decision (EU) 2025/2371 · 21 CFR Part 820 (QMSR) · ISO 13485:2016 · COM(2025) 1023

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