COMPANION RESOURCE — REGULATORY OPERATIONS

90-Day EU MDR Catch-Up Checklist

A working document for VPs of Regulatory Affairs, Quality Directors, and Compliance leads at Class II/III device manufacturers who are behind schedule on EU MDR submission.

How to use: Print this page. Bring it to your next RA/QA planning meeting. Walk your team through the four sections in order. Check the boxes you can defend today; flag the rest as blocking, findable, or polish gaps.

PHASE 1 — DAYS 1–15

Gap Triage (Not Gap Analysis)

- ■ **Run AI-assisted extraction pass** on existing technical files, DHF, and CER to auto-populate the triage grid.
- ■ **Sort every deliverable into three buckets:** Blocking (notified body will refuse to review), Findable (deficiency letter, not rejection), Polish (fix during response cycles).
- ■ **Assign single owner + due date** to every blocking gap. No exceptions.
- ■ **Kill all meetings that don't produce written output** — weekly checkpoint + dashboard only.

PHASE 2 — DAYS 16–45

Attack Blocking Gaps First

Priority	Deliverable	What auditors expect in 2026
HIGH	Clinical Evaluation Report (CER)	Literature search refreshed within last 24 months; post-market data integrated.
HIGH	GSPR Conformity Matrix	Fully traced matrix (not claim table); rebuild if predates 2023.
MED	Post-Market Surveillance Plan	Active plan with data flow to CER and risk file.
MED	PMCF Plan and Report	Justified plan aligned to device class and residual risk.
MED	Risk Management File (ISO 14971)	Updated with post-market data; not stale since 2021.
LOW	Labeling & IFU	Aligned to Annex I, Chapter III; language coverage complete.

PHASE 3 — DAYS 46–75

Parallel Remediation With a 3-Person Pod

Role	Responsibility	Output leverage
Regulatory Lead	Owns notified body strategy, submission decisions, deficiency responses.	Judgment work — no AI replacement
QA / Doc Specialist	Owns technical file assembly, formatting, traceability.	AI-assisted drafting cuts author time 50–70%
Clinical Writer	Owns CER, PMCF, and clinical narrative rewrites.	AI first-draft + human polish = 3× throughput

PHASE 4 — DAYS 76–90

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Pre-Submission Dry Run

- ■ **Mock notified body review** with a former reviewer or certified consultant.
- ■ **Prep response templates for the top 20 likely deficiency questions** in your device class using AI-assisted drafting.
- ■ **Assemble final submission package** with version-controlled artifacts and traceability log.
- ■ **Submit.**

WHAT TO AVOID

- ✗ **Don't rewrite what you can update.** Version-control your CER; don't restart it.
- ✗ **Don't buy a new eQMS mid-remediation.** Fix documents first, evaluate systems later.
- ✗ **Don't rely on offshore doc vendors alone.** Fine for formatting, weak on regulatory judgment.

Want to pressure-test your MDR catch-up plan?

Book a free 30-minute working session at alterra-ai.com/contact. No pitch — a working conversation with someone who has run MDR remediation before.

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