

KNOW YOUR OBLIGATIONS. DISTRIBUTE WITH CONFIDENCE.

Turnkey QMS Starter Kit designed specifically for medical device importers & distributors.

Translate EU MDR/IVDR economic operator obligations into clear responsibilities, robust controls and demonstrable compliance.

YOUR CHALLENGES



AMBIGUITY OF OPERATOR ROLES Which EU MDR/IVDR Article 13 & 14 obligations actually apply to your supply chain?



OPERATIONAL CONTROL How to translate EU MDR/IVDR distributor obligations into consistent, documented processes across day-to-day operations?



IMPLEMENTATION BURDEN How to build an defensible Quality Management System (QMS) without creating heavy operational bottlenecks?

OUR APPROACH

01 ASSESS

- Assessment of device flows, storage, and operator status
- Gap analysis for EU MDR/IVDR Articles 13 & 14
- Customized compliance roadmap and streamlined execution plan



02 IMPLEMENT

- Rapid deployment of SOPs and verification logs
- Tailored workshops for supply chain, warehouse, and quality teams
- Mock inspections and audit support



03 ASSURE

- Focused training on EU MDR/IVDR quality and traceability
- Support for ISO 13485:2016/A11:2021 certification
- On-demand quality assurance & regulatory affairs (QA/RA) hotline for quick query resolution

YOUR BENEFITS



ROLE CLARITY & REGULATORY ALIGNMENT

Establish an accurate regulatory scope and fully compliant operations aligned with mandatory Article 13 & 14 requirements.



CONTROLLED & TRACEABLE PROCESSES

Embed compliant workflows for verification, storage, distribution, complaints and regulatory interactions.



AUDIT & INSPECTION READINESS

Ensure end-to-end supply chain traceability and lean, defensible workflows built for smooth inspector approval.

**READY TO ASSESS YOUR
DISTRIBUTION COMPLIANCE?**

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