

■ WHY CE MARKING IS JUST THE STARTING LINE

A Strategic Guide to Entering Germany's MedTech Market

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1. EXECUTIVE SUMMARY

Germany is Europe's largest single-country MedTech market, with a volume exceeding €41 billion in 2024 and structurally growing demand driven by an aging population.[1] For international manufacturers, it represents one of the most rewarding—and most demanding—market opportunities worldwide.

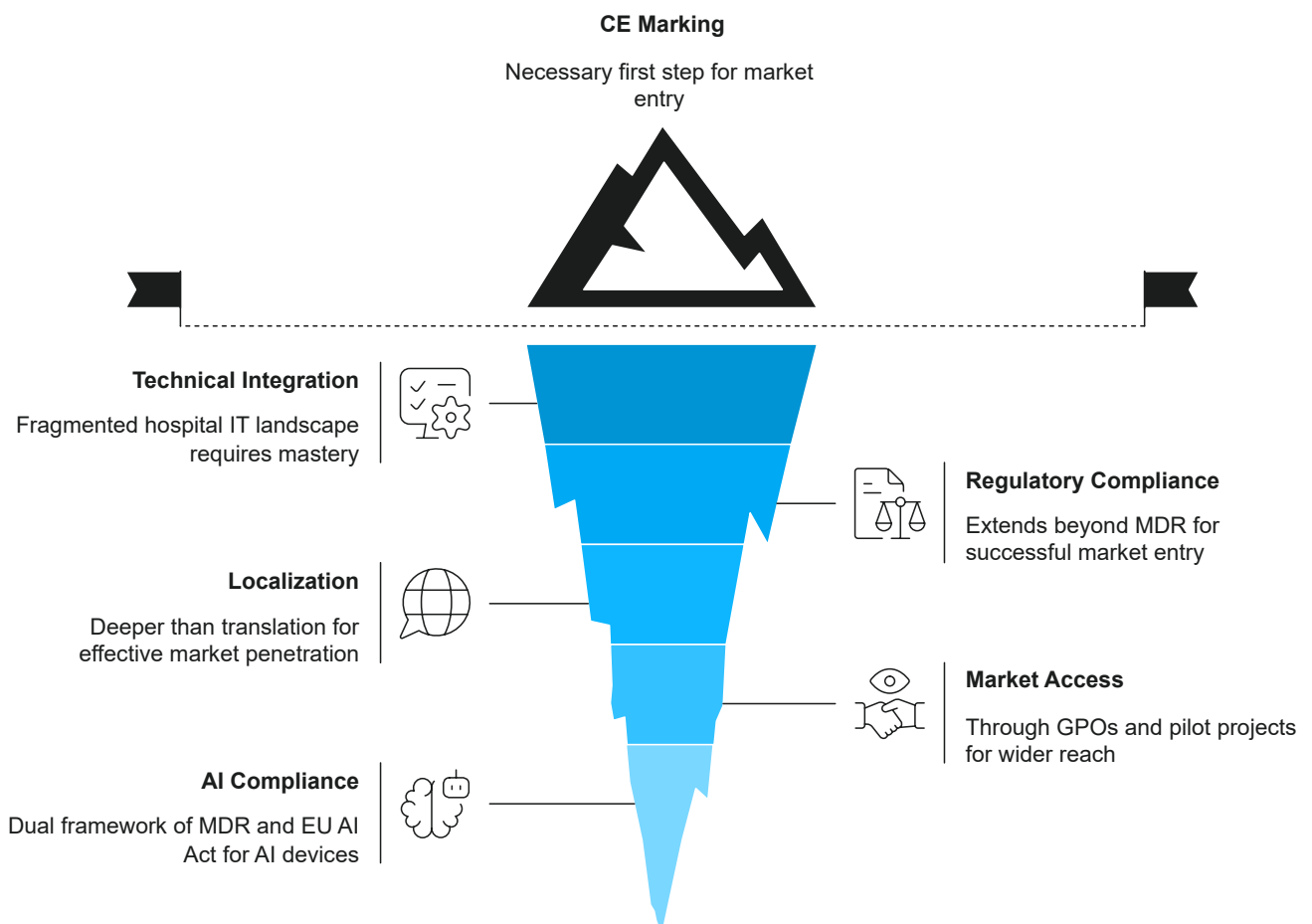
Achieving CE marking under the Medical Device Regulation (MDR) is a necessary first step, but it is far from sufficient. Successful market entry in Germany requires the simultaneous mastery of five interdependent domains:

1. Technical integration into a uniquely fragmented hospital IT landscape
2. Regulatory compliance that extends well beyond MDR
3. Localization that goes deeper than translation
4. Market access through Group Purchasing Organizations (GPOs) and pilot projects
5. For AI-enabled devices, compliance with the dual framework of MDR and the EU AI Act



This whitepaper provides decision-makers at international MedTech companies with a structured orientation across these five dimensions. It offers frameworks, critical decision points, and actionable pointers for strategic planning—grounded in the realities of the German healthcare ecosystem as of early 2026.

Successful German MedTech Market Entry Requires More Than CE Marking



2. KEY TAKEAWAYS AT A GLANCE

■ Market scale

Germany accounts for approximately 43% of the European MedTech market. However, domestic growth has been low for years (roughly 1.0% in 2024), while hospital financial pressure is intensifying.^[1]

■ CE marking ≠ market access

Commercial success depends on integration readiness, localization, and a viable reimbursement strategy—not certification alone.

■ Fragmented hospital IT

No single HIS platform covers more than approximately 40% of German hospitals. Every integration is an individual project.^[2]

■ MDR + AI Act convergence

AI-based medical devices face dual regulatory requirements. Parallel compliance planning avoids duplicate documentation and audit gaps.^[3]

■ GDPR's German complexity

Germany's layered data protection regime (federal + state + ecclesiastical law) has no direct parallel in other EU markets.^[4]

■ Pilot projects are prerequisites

German clinics and GPOs require local clinical evidence and reference installations before entering framework agreements.

■ Window of opportunity

The SAP IS-H phase-out (affecting 250+ hospitals by 2030) and the rollout of the Electronic Patient Record (ePA) are creating unprecedented openings for interoperable new entrants.