

Germany's Trilateral AI Regulatory Sandbox Pilot — Simulating an AI Act Sandbox With Two Medical-Device Start-ups

AI in the Public Sector · Good practice · Germany

Quality score: 53/100

Evidence strength: Moderate

Summary

Seven-month pilot (from May 2025) in which three German authorities simulated an EU AI Act regulatory sandbox with two medical-device companies, ahead of the August 2026 deadline; it produced exit reports, an AI Act/MDR roadmap and a public final report.

Key dimensions

Dimension	Score
Evidence of impact / measured public value	1/3
Transparency, fairness & accountability	2/3
Transferability / demonstrated replication	2/3
Scalability beyond pilot	1/3
Governance, capability & sustainability	2/3

Evaluated by C-NAPSE

Data sources

[C-NAPSE web research](#) — accessed 2026-10-16

[Bundesnetzagentur, Hessian Ministry for Digitalisation and Innovation, Federal Commissioner for Data Protection and Freedom of Information](#) — accessed 2026-10-16

[Bundesnetzagentur press release \(17 Mar 2026\)](#) — accessed 2026-10-16

[ZEVEDI final report \(PDF\)](#) — accessed 2026-10-16

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