



NAVIGATING ACCOUNTABILITY

A THRESHOLD TYPOLOGY FOR HEALTHCARE WORKERS' LIABILITY IN AI-ASSISTED MEDICAL
DECISION-MAKING UNDER EU LAW

PROFESSOR MARIJA AMPOVSKA

GOCE DELCEV UNIVERSITY STIP, NORTH MACEDONIA



INTRODUCTION – THE CHALLENGE

- Rapid integration of AI in healthcare
- Paradigm shift in medical liability
- Problem: Opacity of AI systems complicates accountability
- Need: Clear legal framework under EU law
- **Research Question:** How do EU instruments define liability thresholds for healthcare professionals using AI?

RESEARCH METHODOLOGY & SCOPE

Method: Doctrinal legal analysis

Focus: Five core EU instruments:

AI Act

Revised Product
Liability Directive
(rPLD)

Proposed AI
Liability Directive
(AILD)

GDPR

Medical Device
Regulation (MDR)

Limitations: EU-level focus; national malpractice law considered only where intersecting with EU law

Judicial practice and empirical evidence, are acknowledged but remain outside the scope of this research

PROPOSED FRAMEWORK: THE THRESHOLD TYPOLOGY

Three liability thresholds:

Key Insight: Liability is layered, context-dependent, and role-specific (user, overseer, modifier)

Regulatory Threshold –
Preventive duties (AI Act,
GDPR, MDR)

Professional Threshold –
Fault-based liability
(national malpractice law
+ AILD)

Product Threshold – Strict
liability (rPLD)



AIRD STATUS CHANGED FROM THE MOMENT OF RESEARCH TILL NOW

PROPOSAL OFFICIALLY WITHDREW IN OCTOBER 2025.

CONCLUSION

