# CRITERIA FOR CROSSING THE PRODUCT LIABILITY THRESHOLD FOR A SUBSTANTIAL MODIFICATION OF MEDICAL ARTIFICIAL INTELLIGENCE

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# ARTICLE 8 RPLD IN REGULATORY CONTEXT

**Directive (EU) 2024/2853 – Revised Product Liability Directive**

**Adopted:** 23 October 2024

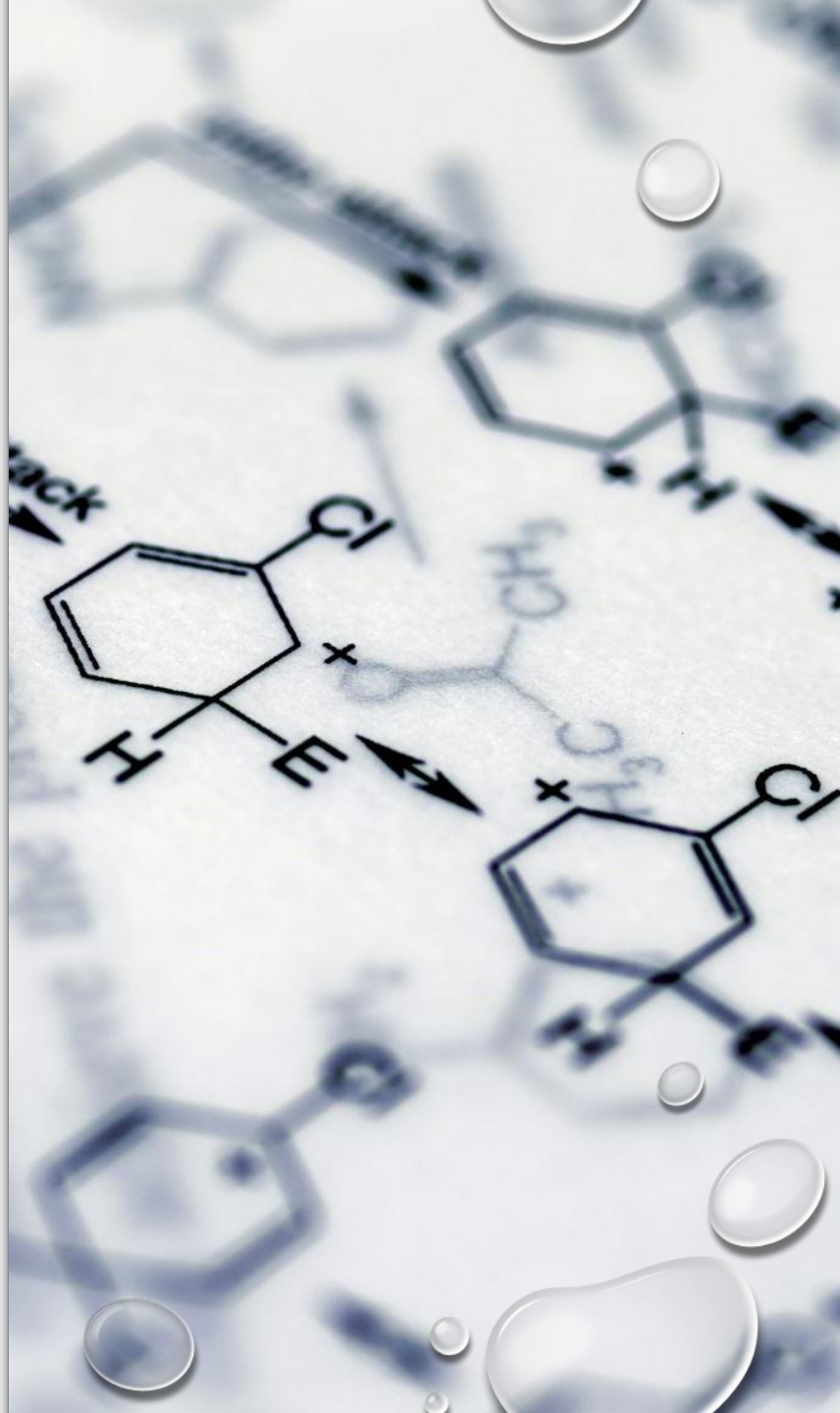
**The novelty:** First product liability directive to explicitly address substantial modification

# THE PROBLEM BEFORE RPLD – FRAGMENTED LANDSCAPE

| Instrument | Addressed Modification? | Purpose |
|---|---|---|
| **MDR** (2017) | Yes – but indirect ("significant changes," Art. 120(3c)) | Safety/compliance |
| **GPSR** (2023) | Yes – detailed definition (Art. 13(3)) | Safety/risk assessment |
| **AI Act** (2024) | Yes – conformity-based definition (Art. 3(23)) | Provider obligations |
| **Old PLD** (1985) | **NO** | Liability |

# ARTICLE 8 RPLD – THE NORM

- *"ANY NATURAL OR LEGAL PERSON THAT SUBSTANTIALLY MODIFIES A PRODUCT* ***OUTSIDE THE ORIGINAL MANUFACTURER'S CONTROL*** *AND THEREAFTER MAKES IT AVAILABLE ON THE MARKET OR PUTS IT INTO SERVICE* ***SHALL BE CONSIDERED A MANUFACTURER*** *OF THAT PRODUCT."*



# GPSR ARTICLE 13(3) – THE THREE CUMULATIVE CRITERIA

| | Criterion | Text |
|---|---|---|
| **1** | Unforeseeability | Changes the product in a manner **not foreseen** in the initial risk assessment |
| **2** | Hazard alteration | Nature of hazard **changes,** a **new** hazard arises, OR **risk level increases** |
| **3** | Non-consumer | Modification **not** made by the consumer themselves |

# CONCLUSION

*"A MODIFICATION DEEMED SUBSTANTIAL UNDER GPSR ARTICLE 13(3) AUTOMATICALLY TRIGGERS MANUFACTURER STATUS UNDER RPLD ARTICLE 8, WITHOUT REQUIRING A SEPARATE ASSESSMENT UNDER THE RPLD"*

# GPSR RECITAL 25 – SOFTWARE UPDATES

*"New technologies might substantially modify the original product, **for instance through software updates**."*

**Consequence:** Such modifications "should then be subject to a **new risk assessment**"

**Significance for medical AI:** Algorithm updates, retraining, and version changes can constitute substantial modification – even without physical intervention

# RPLD'S DIRECTION ON ESTABLISHING SUBSTANTIAL MODIFICATION

- **RECITAL 39 RPLD PROVIDES A CLEAR THREE-STEP HIERARCHY:**

| Step | Direction | Source |
|---|---|---|
| **1** | Apply criteria from **Union product safety law**(GPSR) | "including Regulation (EU) 2023/988" |
| **2** | Apply criteria from **national product safety law** | If Union law provides none |
| **3** | Apply **fallback test** | Only where no criteria exist |

# CONCLUSION ON MDR

*"THE MDR'S INTENDED PURPOSE AND THE AI ACT'S TRUSTWORTHINESS REQUIREMENTS DIRECTLY INFORM THE RPLD'S CENTRAL QUESTION OF DEFECTIVENESS"* – BUT NOT THE DEFINITION OF SUBSTANTIAL MODIFICATION