QTICS GROUP

PROFESSIONAL.INTELLIGENT.HUMAN

Practical consequeces of AI Act for Medical Device Regulation

@ Mental Health and AI – hybrid workshop, Budapest Technical University, 27th Nov 2024

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WHO IS TALKING, BASED ON WHAT?

https://www.qtics.group/

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a QTICS Group Zrt. founder

- electrical engineer & economist
- 15 years in the Testing, Inspection & Certification sector
- One of the widest certification competence in Europe

  → **10+ EU Notified Body domains** in the Group (NB 2102 & NB 2806)

  → **~100 employed & ~100 contracted experts**, + Universities (SE,BME,ÓE,..)

„INNOVATIO NECESSE EST, VIVERE NON EST NECESSE…”

“After all, all devices have their dangers.”

The discovery of fire introduced cooking—and arson. The discovery of the compass improved navigation—and destroyed civilizations in Mexico and Peru. The automobile is marvelously useful—and kills Americans by the tens of thousands each year. Medical advances have saved lives by the millions—and intensified the population explosion.”

— Isaac Asimov, Robot Visions

„THE DISCOVERY OF SPEECH INTRODUCED COMMUNICATION — AND LIES”

EU's regulatory approach:

- **The EU MDR Regulation:** medical devices must be classified into classes
- **EU AI-ACT:** 4 risk categories
- **The EU CSA/CRA Regulations:** cybersecurity compliance certification requirements **+ GDPR!!!**
- **EU Product Liability Directive:** harmonizes manufacturer's liability for defective AI products (creates rebuttable presumptions to assist the injured party)
- **Mandatory Tests & Certification:** but who can test and who can certify? Based on what? Who inspects the inspectors?
- **Other regulatory elements:** EC Representative, Unique Database registration, Market Surveillance Authority, Notified Body, etc..

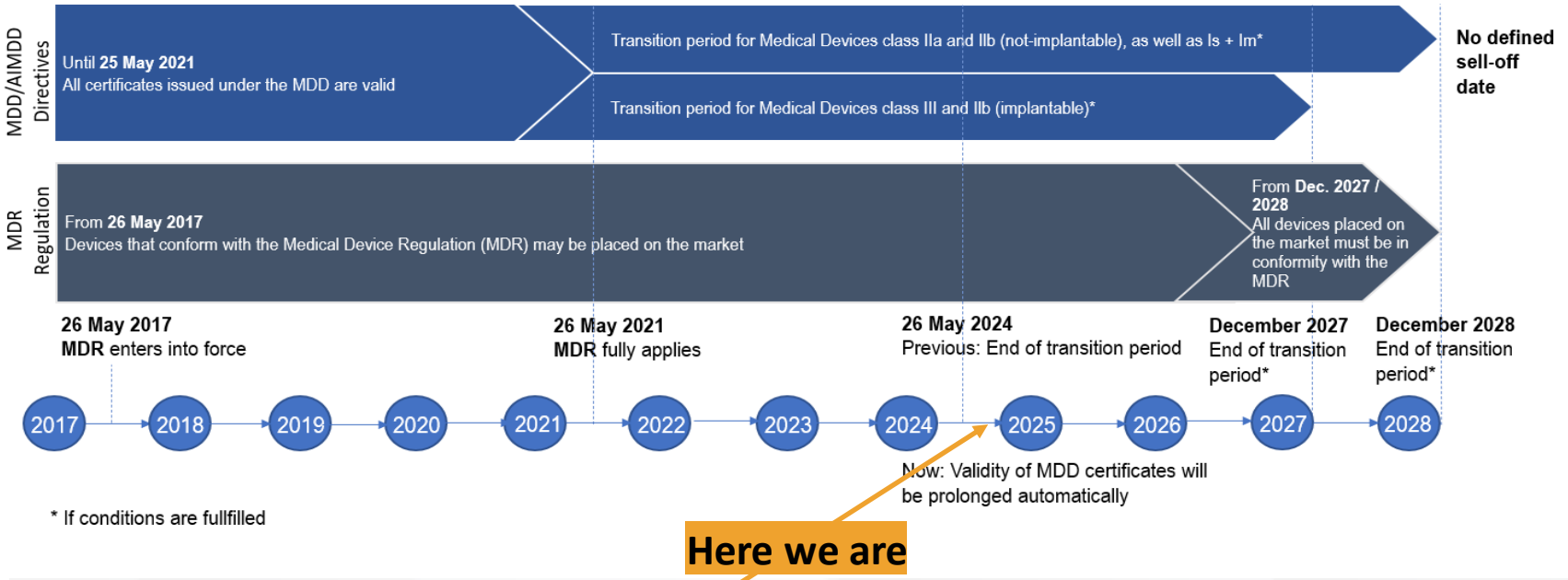
MEDICAL DEVICES – HIGH RISK!

The AI-ACT classifies MDR's active device categories as such "per se".

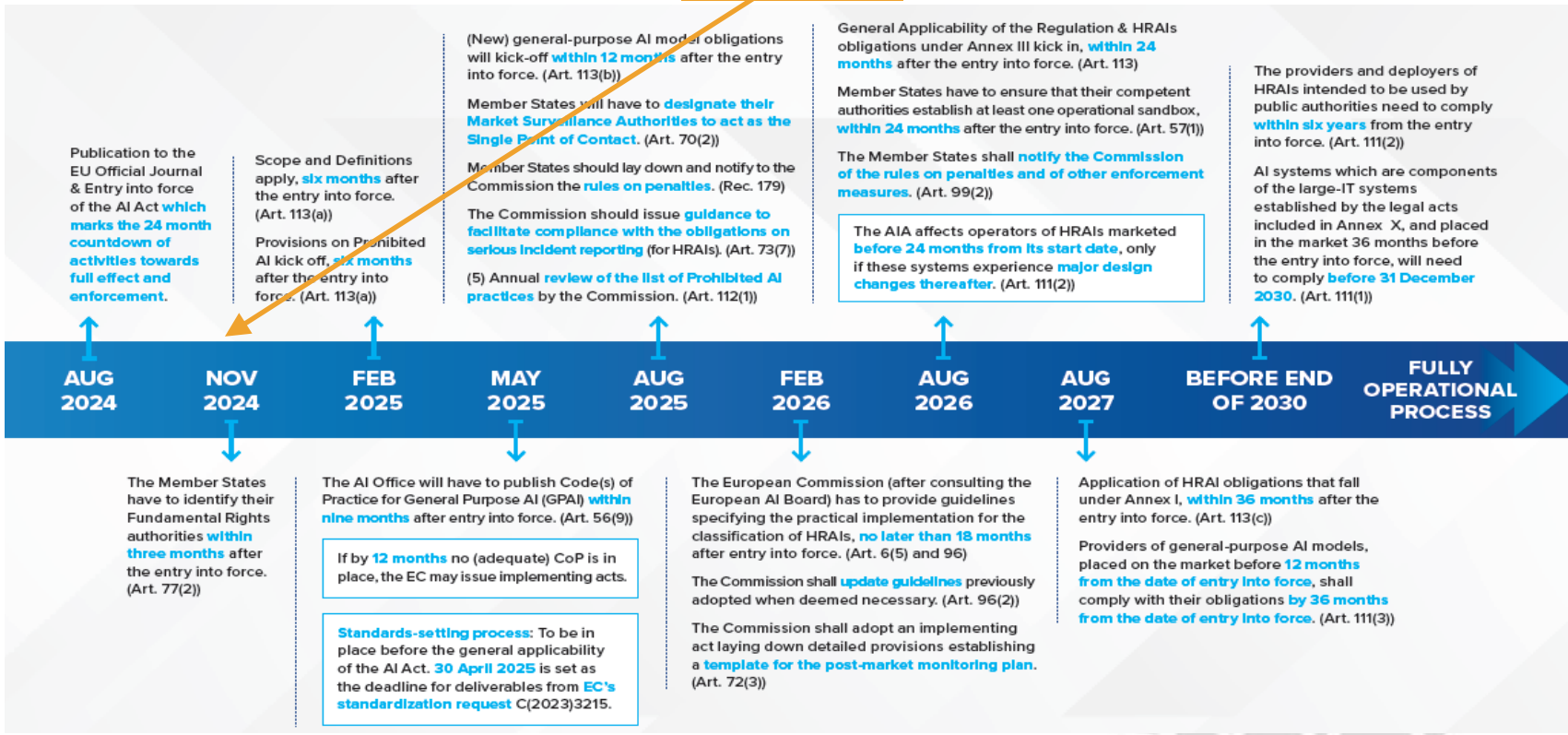
AI ACT timeline

vs.

MDR timeline



Here we are



Challenges of conformity assessment AI-ACT & MDR

Challenge 1: The intersection of a lengthy certification process and rapid iteration cycles.
The innovation cycle for AI-based applications is much faster than for physical devices or even traditional software. Finding efficient certification processes within the existing MDR pathway is key to ensure timely integration of the most advanced models.

Challenge 2: Little room for continuous adaptation
Under the MDR, medical devices must be "frozen" during certification and can only be modified within a very specific range without recertification. Neural networks are constantly improving based on new input after deployment, AI-based models and products may change even after they are on the market (e.g. LLM-based solutions). Changing the basic model will result in a change in the behavior of the application even though it is already in use.

Challenge 3: There are no standardized approaches to AIaMDSW certification
AI certification presents new technical challenges (e.g. unjustified bias, unfathomable models, transparency and traceability. **There are no harmonized standards** or common criteria, the lack of which hampers systematic monitoring of the compliance of evolving models and rapid iteration.

Challenges of conformity assessment AI-ACT & MDR

How is it from a given TOE's point of view for AI driven Medical Devices?

Challenge 4: Potential conflicts due to different classification categories in AI-ACT vs. MDR

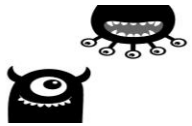
Example:

- There are 4 risk categories defined in the EU AI act, and by **MDR** Class III 3 'high-risk' devices include most medical AI devices. (That's because most AI as a Medical Device performs clinical decision support or diagnosis.)

  Are there medical device producers for 'unacceptable risk' devices such as emotion detection and biometric categorization which are banned under the new **AI-Act**?

  Mental health curing may require such technologies – e.g. emotion detection!

HM??



Challenges of conformity assessment AI-ACT & MDR

Effects of AI-Act & MDR from an AI-based Mental Health Device producers's point of view

- **Clinical Evaluation and AI-Specific Considerations – I:**
- Both the **AI Act** and the **MDR** emphasize clinical evaluation, but there are **specific implications for AI-driven mental health devices**.
- **EU MDR Clinical Evaluation & Clinical Evaluation of AI-Based Devices**: Under the MDR, mental health devices with AI functionality (e.g., an AI-based diagnostic tool for assessing mental health conditions such as depression or bipolar disorder) must undergo a **clinical evaluation** to demonstrate their safety, performance, and intended use.
    - **Mental Health Applications**: For instance, a device using AI to assist in diagnosing depression or anxiety must prove its **clinical validity** (whether it accurately identifies mental health conditions), **clinical performance** (how effective it is in practice), and **safety** (ensuring it doesn't cause harm to patients).
    - **Real-World Validation**: AI systems in mental health devices should have clinical data supporting their accuracy and efficacy. If an AI tool makes therapeutic suggestions or diagnoses, the device must demonstrate its medical effectiveness via clinical trials or substantial evidence of its clinical validity.

Challenges of conformity assessment AI-ACT & MDR

Effects of AI-Act & MDR from an AI-based Mental Health Device producers's point of view

- **Clinical Evaluation and AI-Specific Considerations - II**
- **EU AI Act and Transparency:**
- One of the key provisions of the **AI Act** that impacts clinical evaluation is the **transparency requirement**: manufacturers must ensure their AI systems are interpretable by users (healthcare professionals and patients), especially when it comes to medical decisions.
  - **Explainability**: For instance, if an AI system diagnoses a mental health disorder such as schizophrenia or autism, the system must explain the rationale behind its decision-making to the medical professional or even to the patient. This can have significant implications in terms of compliance with both regulations, particularly if the AI's recommendations are to influence treatment plans.

Objectivity & comparability → Need for standards!

Standards: ISO has already delivered multiple AI related standards:

- ISO/IEC 22989, which defines the terminology for artificial intelligence;
- ISO/IEC 23053, which provides a framework for AI and machine learning;
- ISO/IEC 23894, which provides guidelines for AI-related risk management.

ISO/IEC 42001 → for comprehensive AI management system conformity

Standardisation: ISO/IEC JTC 1/SC 42

A standards subcommittee of the Joint ISO/IEC JTC 1 Technical Committee of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

ISO/IEC JTC 1/SC 42 develops international standards, technical reports and technical specifications in the field of artificial intelligence.

The international secretariat of ISO/IEC JTC 1/SC 42 is the American National Standards Institute (ANSI) in the United States of America.

ISO/IEC Standard	Title	Status
ISO/IEC 8183	ISO/IEC 8183: Artificial intelligence -- Data life cycle framework	Published (2023)
ISO/IEC 20547-1	ISO/IEC 20547-1: Big data reference architecture -- Part 1:Framework and application process	Published (2020)
ISO/IEC 20547-2	ISO/IEC TR 20547-2:2018 : Big data reference architecture -- Part 2: Use cases and derived requirements	Published (2018)
ISO/IEC 20547-3	ISO/IEC 20547-3: Big data reference architecture -- Part 3: Reference architecture	Published (2020)
ISO/IEC 20547-5	ISO/IEC TR 20547-5:2018: Big data reference architecture -- Part 5: Standards roadmap	Published (2018)
ISO/IEC 20546	ISO/IEC 20546: Big data -- Overview and vocabulary	Published (2019)
ISO/IEC 22989	ISO/IEC 22989: Artificial Intelligence Concepts and Terminology	Published (2022)
ISO/IEC 23053	ISO/IEC 23053: Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)	Published (2022)
ISO/IEC 23894	ISO/IEC 23894: Artificial intelligence - Guidance on risk management[12]	Published (2023)
ISO/IEC TR 24368	ISO/IEC TR 24368: Overview of ethical and societal concerns[13]	Published (2022)
ISO/IEC 24668	ISO/IEC 24668: Process management framework for big data analytics	Published (2022)
ISO/IEC TS 4213	ISO/IEC TS 4213: Assessment of Machine Learning Classification Performance[14]	Published (2022)
ISO/IEC 24029-1	ISO/IEC TR 24029-1: Assessment of the robustness of neural networks — Part 1: Overview	Published (2021)
ISO/IEC 24029-2	ISO/IEC 24029-2: Assessment of the robustness of neural networks — Part 2: Methodology for the use of formal methods [15]	Published (2023)
ISO/IEC TR 24027	ISO/IEC TR 24027: Bias in AI systems and AI aided decision making	Published (2021)
ISO/IEC 25059	ISO/IEC 25059: Quality model for AI systems	Published (2023)

Alignment of the AI ACT and the MDR regulation:

Alignment with existing sectoral regulations, in our case the MDR rules, is particularly important.
This alignment ensures that the AI-Act does not operate in isolation but complements and integrates the wider regulatory framework. The AI Act must not leave critical areas ambiguous, ineffective or even contradictory regulation, **such as the use of medical AI as a priority area.**

Compliance with sectoral legislation should lead to a presumption of compliance with similar rules in the AI Act.
Recital (54) states that "Providers of high-risk AI systems which are subject to quality management system obligations under the relevant sectoral EU legislation shall be given the possibility to **incorporate the elements** of the quality management system provided for in this Regulation (AI-ACT) as part of an existing quality management system provided for in the relevant other sectoral EU legislation".

It will be important to develop an accurate mapping between the existing MDR rules and the AI-ACT rules that are expected to be met if the sectoral rules are met.

HORIZONTAL ⟺ **VERTICAL!**

Responsibility of the Engineer (AI-ACT):

Accuracy, robustness and cybersecurity

(Chapter 2, article 15)

HUMAN OVERSIGHT

Of course, we also try to solve this with an AI "turbo"... In other words, the AI tests and monitors the AI...