contextflow

See beyond a single case.

EU Artificial Intelligence Act

presented by

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Chief Quality Officer

Agenda

- Introduction to contextflow and AI-based MDSW

- Artificial Intelligence Act EU
  - AI Medical Device Regulatory Landscape
  - Classification of AI
  - Requirements for High Risk AI

- Relation to MDR (EU) 2017/745

- Role of QMS

- Challenges

- ?Status QUO?

contextflow

Manufacturer

contextflow GmbH
Margaretenstraße 70/2/8
1050 Vienna, Austria
FN 455935v, DVR 0037257

Product Identification

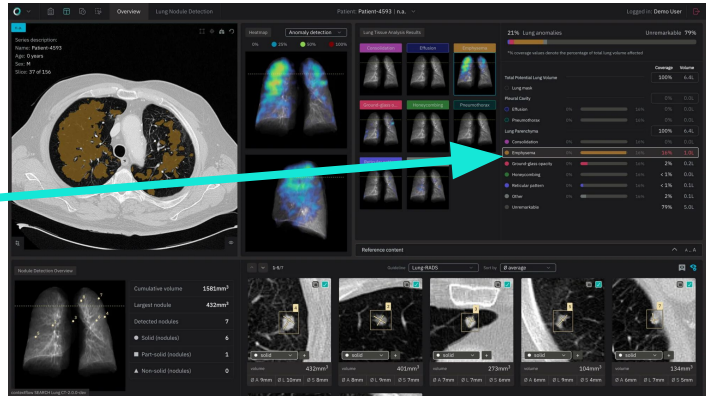
CE 0123

contextflow ADVANCE Chest CT
Medical Device Software (MDSW)
MDR Class IIa

Intended Use

contextflow ADVANCE Chest CT

- is an AI-based, Computer Aided Detection (CADe) system for 3D medical imaging data.
- provides
  - ***qualitative and quantitative analysis results*** and
  - corresponding ***reference information*** relevant for the ***identification and interpretation*** of
    - ***lung-specific image patterns*** in ***CT*** (Computed Tomography) scans.



Quality Criteria for MDSW

Quality Criteria for MDSW

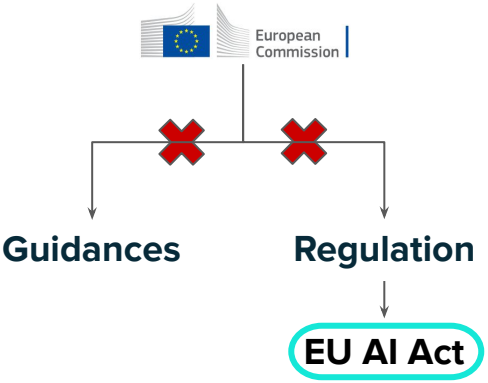
Core requirements for medical device software development

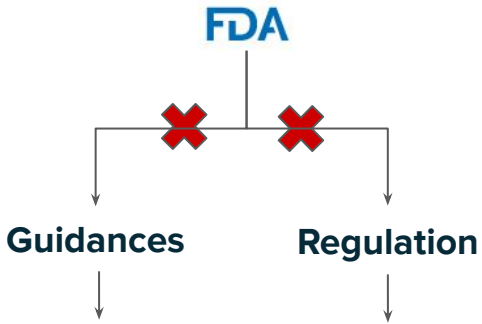
- EN ISO 13485 Medical devices - quality management systems
- IEC 62304 Medical device software - Software life cycle processes
- IEC 82304-1 Health software - Part 1 general requirements for product safety
- EN ISO 14971 Medical devices - Application of risk management to medical devices
- IEC 62366-1 Medical devices - Part 1 Application of usability engineering to medical devices

Data, data, data...

- **EU AIA (Artificial Intelligence Act)**

AI Medical Device Regulatory Landscape





DRAFT Marketing Submission Recommendations for a Predetermined Change Control Plan for AI/ML-Enabled Device Software Functions (April 2023)

AI Bill of Rights

- Blueprint on October 4, 2022 by White House

ISO

- ISO/IEC 23053:2022
  - Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)
- ISO/IEC TR 24027:2021 → **Technical Report**
  - Information technology — Artificial intelligence (AI) — Bias in AI systems and AI aided decision making
- ISO/IEC TR 24028:2020 → **Technical Report**
  - Information technology — Artificial intelligence — Overview of trustworthiness in artificial intelligence
- ISO/IEC TR 24029-1:2021 → **Technical Report**
  - Artificial Intelligence (AI) — Assessment of the robustness of neural networks — Part 1: Overview
- ISO/IEC 24029-2:2023
  - Artificial intelligence (AI) — Assessment of the robustness of neural networks — Part 2: Methodology for the use of formal methods
- ISO/IEC AWI 24029-3 → **NOT PUBLISHED**
  - Artificial intelligence (AI) — Assessment of the robustness of neural networks — Part 3: Methodology for the use of statistical methods
- ISO/IEC TR 29119-11:2020 → **Technical Report**
  - Software and systems engineering — Software testing — Part 11: Guidelines on the testing of AI-based systems

AI Medical Device Regulatory Landscape

GMLP: Good Machine Learning Practice for Medical Device Development: Guiding Principles

- The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA)
  - have jointly identified 10 guiding principles that can inform the development of GMLP

EU Artificial Intelligence Act

General Information: Purpose & Scope

Purpose of regulation

- To ensure the protection of fundamental rights and user safety
- To enhance trust in the development and uptake of AI

Scope of application

- To both public and private actors inside and outside the EU
  - As long as the AI system is placed on the Union market **or**
  - Its use affects people located in the EU

General Information: Definition of AI system acc. AI Act

‘artificial intelligence system’ (AI system) means software

- that is developed with one or more of the techniques and approaches listed in Annex I and

- can, for a given set of human-defined objectives,
  - generate outputs such as
    - content,
    - predictions,
    - recommendations, or
    - decisions influencing the environments they interact with

General Information: AI Techniques

Types of AI techniques covered by the AI Act Article 3/Annex I

- Machine learning approaches including:
  - supervised, unsupervised and reinforcement learning
  - using a wide variety of methods including deep learning

- Logic- and knowledge-based approaches, including:
  - knowledge representation
  - inductive (logic) programming
  - knowledge bases
  - inference and deductive engines
  - (symbolic) reasoning and expert systems

- Statistical approaches, Bayesian estimation, search and optimization methods

Regulation Architecture: Articles

TITEL	CHAPTER	ARTICLE
TITLE I: GENERAL PROVISIONS	N/A	Article 1-4
TITLE II: PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES	N/A	Article 5
TITLE III HIGH-RISK AI SYSTEMS	Chapter 1 Classification Of AI Systems As High-risk	Article 6-7
	Chapter 2 Requirements For High-risk AI Systems	Article 8-15
	Chapter 3 Obligations Of Providers And Users Of High-risk AI Systems And Other Parties	Article 16-29
	Chapter 4 Notifiying Authorities And Notified Bodies	Article 29-39
	Chapter 5 Standards, Conformity Assessment, Certificates, Registration	Article 39-51
TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS	N/A	Article 52
TITLE V MEASURES IN SUPPORT OF INNOVATION	N/A	Article 53-55

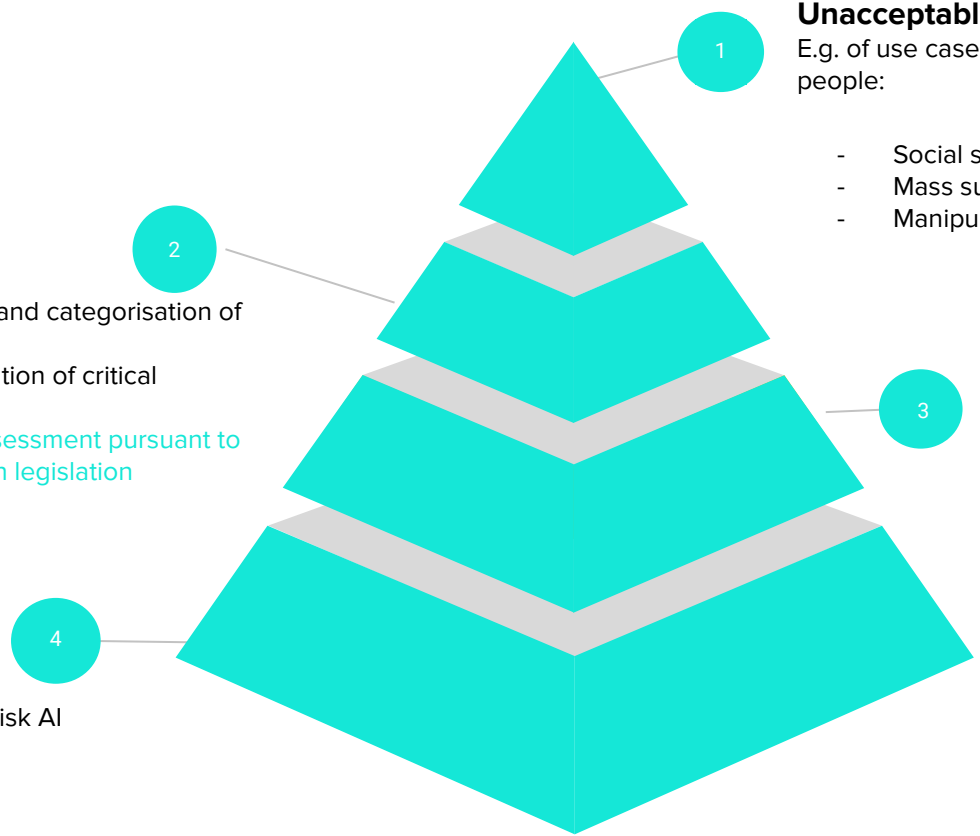
Regulation Architecture: Articles

TITEL	CHAPTER	ARTICLE
TITLE VI GOVERNANCE	Chapter 1 European Artificial Intelligence Board	Article 56-58
	Chapter 2 National Competent Authorities	Article 59
TITLE VII EU DATABASE FOR STAND-ALONE HIGH-RISK AI SYSTEMS	N/A	Article 60
TITLE VIII POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE	Chapter 1 Post-market Monitoring	Article 61
	Chapter 2 Sharing Of Information On Incidents And Malfunctioning	Article 62
	Chapter 3 Enforcement	Article 63-68
TITLE IX CODES OF CONDUCT	N/A	Article 69
TITLE X CONFIDENTIALITY AND PENALTIES	N/A	Article 71-72
TITLE XI DELEGATION OF POWER AND COMMITTEE PROCEDURE	N/A	Article 73-74
TITLE XII FINAL PROVISIONS	N/A	Article 75-85

Regulation Architecture: Annexes

ANNEX	DESCRIPTION
ANNEX I	Artificial Intelligence Techniques And Approaches
ANNEX II	List Of Union Harmonisation Legislation
ANNEX III	High-risk AI Systems Referred To In Article 6(2)
ANNEX IV	Technical Documentation Referred To In Article 11(1)
ANNEX V	EU Declaration Of Conformity
ANNEX VI	Conformity Assessment Procedure Based On Internal Control
ANNEX VII	Conformity Based On Assessment Of Quality Management System And Assessment Of Technical Documentation
ANNEX VIII	Information To Be Submitted Upon The Registration Of Highrisk AI Systems In Accordance With Article 51
ANNEX IX	Union Legislation On Large-scale It Systems In The Area Of Freedom, Security And Justice

4 Risk Categories



Unacceptable Risk
E.g. of use cases related to safety, livelihoods and rights of people:

- Social scoring
- Mass surveillance
- Manipulation of human behaviour causing harm

High Risk
E.g. of use cases:

- Biometric identification and categorisation of natural persons
- Management and operation of critical infrastructure
- 3rd party conformity assessment pursuant to the Union harmonisation legislation

Limited Risk
E.g. of use cases:

- Chatbots

Minimal Risk
E.g. of use cases:

- Class I acc. MDR low risk AI applications

AI Act Applicability & Classification

Article 3/Annex I

E.g. Deep learning algorithm, knowledge bases, statistical approaches

Article 5

E.g. AI system that causes physical or psychological harm

Annex II

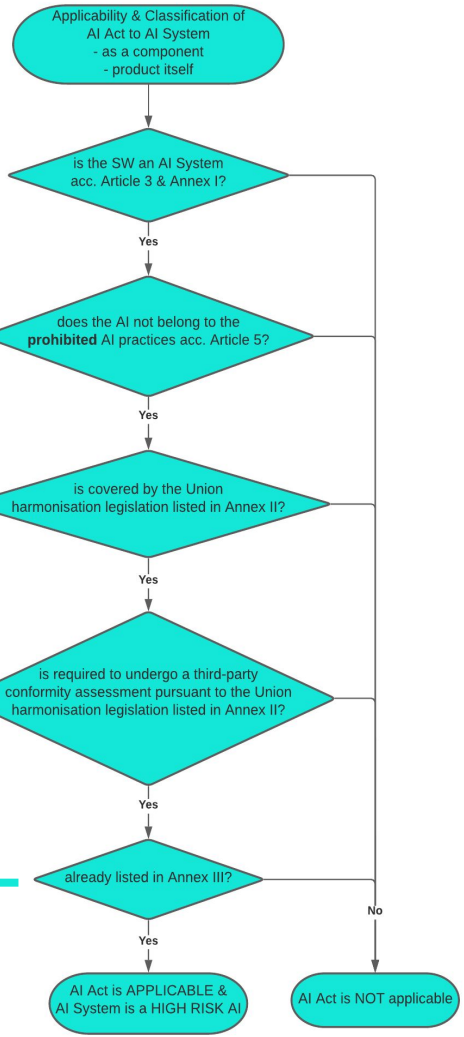
E.g. Regulation (EU) 2017/745 - MDR

E.g. Regulation (EU) 2017/746 - IVDR

Annex III

E.g. Biometric identification and categorisation of natural persons

E.g. Education and vocational training



High Risk AI: Mandatory Requirements

Article & Annex	Description
Article 9	Risk management system
Article 10	Data and data governance
Article 11 & Annex IV	Technical documentation
Article 12	Record-keeping
Article 13	Transparency and provision of information to users
Article 14	Human oversight
Article 15	Accuracy, robustness and cybersecurity
Article 17	Quality management system
Article 49	CE marking of conformity
Article 51	Registration

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AI Act QMS Req. Comparison with MDR

AI Act Article 17	MDR (EU) 2017/745 Article 10(9)
1. (a) a strategy for regulatory compliance	(a) *…a strategy for regulatory compliance*
1. (b) techniques, procedures for the design, design control and design verification	(g) *…product realisation*
1. (c) techniques, procedures for the development, quality control and quality assurance	*…QMS in general*
1. (d) examination, test and validation procedures to be carried out before, during and after the development	*…QMS in general* + (f) *…clinical evaluation*
1. (e) technical specifications, including standards, to be applied	(b) *…GSPR*
1. (f) systems and procedures for data management (e.g. data collection, data analysis, data labelling, data storage, data retention)	*…QMS in general*
1. (g) the risk management system	(e) *…risk management*

AI Act QMS Req. Comparison with MDR

AI Act Article 17	MDR (EU) 2017/745 Article 10(9)
1. (h) the post-market monitoring system	(i) ...*PMS*
1. (i) reporting of serious incidents	(k) ...*reporting serious incidents*
1. (j) communication with national competent authorities, NBs	(j) ...*reporting serious incidents*
1. (k) systems & procedures for record	...*QMS in general*
1. (l) resource management	(g) ...*resource management*
1. (m) management responsibility	(c) ...*management responsibility*

High Risk AI: Mandatory Requirements

Article & Annex	Description
Article 9	Risk management system
Article 10	Data and data governance
Article 11 & Annex IV	**Technical documentation**
Article 12	Record-keeping
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AI Act Technical Documentation Req. Comparison with MDR

AI Act Annex IV	MDR (EU) 2017/745
1. (a) - (g) A general description of the AI system: Instructions for Use	Annex I: GSPRs; Chapter III
2. (a) - (g) A detailed description of the elements of the AI system and of the process for its development	Article 10: General obligations of manufacturers; (4) *...draw up technical documentation* & (9) *...establish QMS*
3. Detailed information about the monitoring, functioning and control of the AI system	Article 83: Post-market surveillance system of the manufacturer
4. A detailed description of the risk management system ➔ Article 9	Annex I (GSPRs); Chapter I
5. A description of any change made to the system through its lifecycle	Annex IX: Conformity Assessment Based On A Quality Management System And On Assessment Of Technical Documentation; Chapter 2
6. A list of the harmonised standards applied	Article 8: Use of harmonised standards
7. A copy of the EU declaration of conformity	Article 10: General obligations of manufacturers; (6)
8. Post-market monitoring (PMM) plan ➔ Article 61(3)	Article 83: Post-market surveillance system of the manufacturer

High Risk AI: Mandatory Requirements

Article & Annex	Description
Article 9	Risk management system
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Role of QMS

Article 10 (2.) AI Act

Data & Data Governance	Processes in QMS	Requirements
(a) relevant design choice (d) data outcome (g) data gaps identification	PD Machine Learning	defines how AI architecture is built • simpler model types
(b) data collection (e) data availability, quantity & suitability of the data sets (f) data biases examination	PD Data Procurement	defines how data sets to be used for ML, test data sets & validation data sets are identified collectected and stored • amount of data • representability of data ➔ avoid bias
(c) data preparation processing operations	PD Data Annotation	defines how data sets are annotated (labelled) • skills for annotators • accuracy of annotations

Article 10 (5.) AI Act

Data & Data Governance	Processes in QMS	Requirements
pseudonymisation, anonymisation, encryption	PD Data Protection & WI Anonymization	defines how to anonymize, encrypt and manage access to data

High Risk AI: Mandatory Requirements

Article & Annex	Description
Article 9	Risk management system
Article 10	Data and data governance
Article 11 & Annex IV	Technical documentation
Article 12	Record-keeping
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Article 15	**Accuracy, robustness and cybersecurity**
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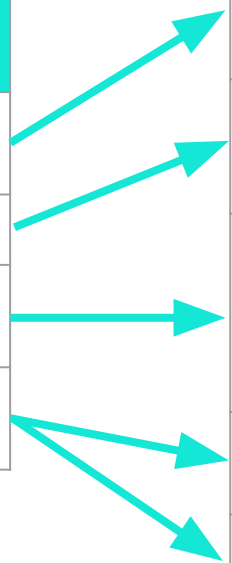
Role of QMS

Article 15 AI Act

Accuracy, Robustness & and Cybersecurity
1. Consistent performance throughout their lifecycle
2. Accuracy metrics in IFU
3. Robustness: backup, fail-safe plans
4. Unauthorized access, cybersecurity risks & vulnerabilities



Processes in QMS	Requirements
PD Operational Review	defines what parameters to consider while performing Information System Activity Review - e.g. audit logs review: logins, file accesses
PD Market Clearance	defines how to perform market clearance for medical devices and which documents to be created - e.g. metrics for predicted vs standard clinical routine
PD Contingency Plan	establishes procedures to enable continuation of critical business processes for protection of data defines how to periodically test and revise contingency plans
PD Data Protection	implements policies and procedures that protect the Data from unauthorized access
PD Cybersecurity Risk Management	manages the cybersecurity risks throughout the system - e.g. vulnerability scoring

Penalties - Administrative Fines

Non-compliance with	Penalties [EUR] for non-compliance
The prohibition of the artificial intelligence practices referred to in **Article 5 (Prohibited AI Practices)** The requirements laid down in **Article 10 (Data & Data Governance)**	**Individual**: up to **30 M** **Company**: up to **30 M** or **6 % of its total worldwide annual turnover** for the preceding financial year, whichever is higher
Any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10	Individual: up to 20 M Company: up to 20 M or 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher
Supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities	Individual: up to 10 M Company: up to 10 M or 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher

Status Quo EU

European Commission

European Parliament

21/04/2021	Legislative proposal published	COM(2021)0206	Summary
07/06/2021	Committee referral announced in Parliament, 1st reading		
16/12/2021	Referral to associated committees announced in Parliament		
16/12/2021	Referral to joint committee announced in Parliament		
11/05/2023	Vote in committee, 1st reading		
22/05/2023	Committee report tabled for plenary, 1st reading	A9-0188/2023	Summary
13/06/2023	Debate in Parliament		
14/06/2023	Decision by Parliament, 1st reading	T9-0236/2023	Summary
14/06/2023	Matter referred back to the committee responsible		

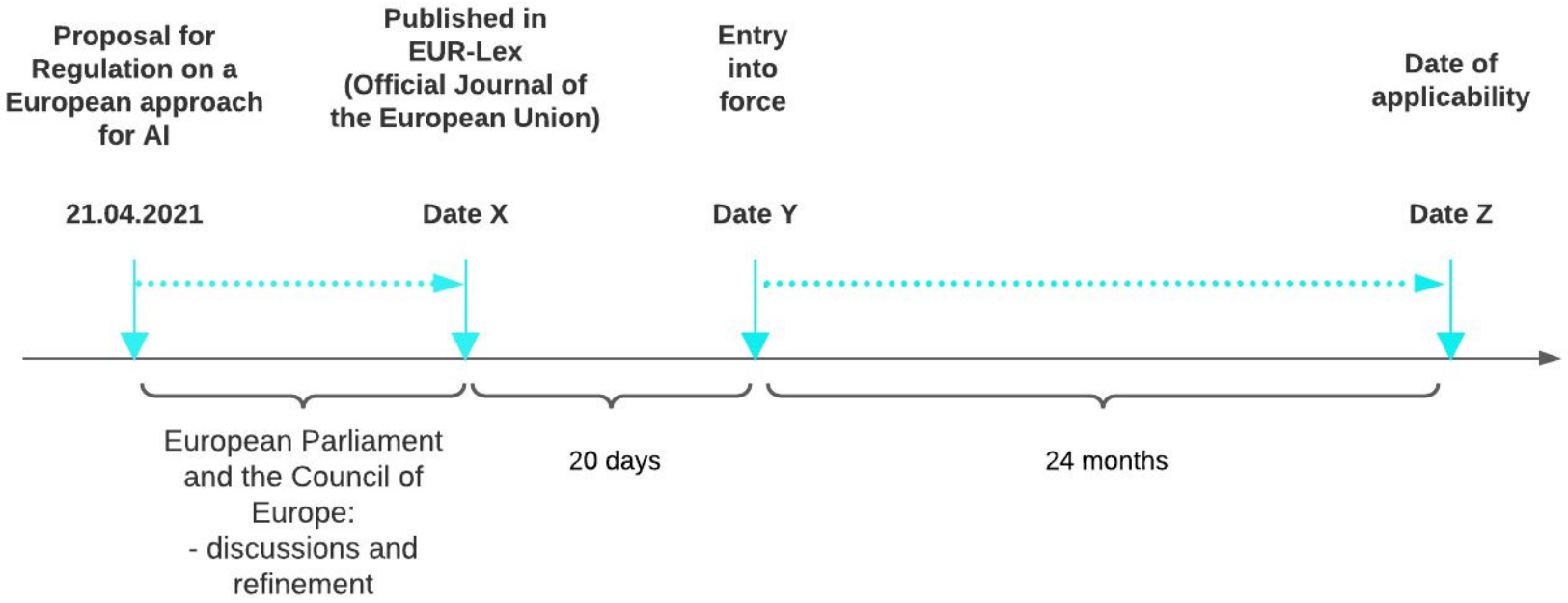
The European Parliament adopted
→ by 499 votes to 28 with 93 abstentions

Trilogue

- **EC, Council of EU & EP**

Source

Status Quo EU



Take-home Message

Class I: ➔ AI Act is NOT applicable

Class IIa & above: ➔ AI Act IS applicable!!!

- If already MDR certified
  - ➔ No major changes in terms of AI implementation, in case of already existing GMLP in the QMS

- Start thinking about
  - Data bias:
    - e.g. Differentiation in training data set, test data set & validation data set
  - Technical Documentation:
    - e.g. TD ML Architecture ➔ ML architecture, embedding of ML components, list of SOUPs

Challenges

- Regulation of adaptive AI

- More clarification is required for AI regulatory sandboxes:
  - for development, testing & validation
  - ➔ E.g. eligibility conditions

- Unavailability of a harmonized ISO Standards across major regulatory bodies

- Very broad scope of the AI Act
  - ➔ covers all "artificial intelligence systems"

- Capacity concerns with the notified bodies to review technical documentation related to AI

- Harmonization of AI regulation is a big issue
  - ➔ EU AI Act, GMLP UK, AI Bill of Rights US, AI Regulation China, etc.

Thank you for your attention!

contextflow

See beyond a single case.

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