Cyber Security and AI

Mr. Robert Froehlich

10th December 2024

Add value.
Inspire trust.

SOFTWARE

Software is the set of computer programs, procedures, and possibly associated documentation and data that are linked to the functioning of a computer system

(IEEE Standard 610.12-1990)

Software is a structured set of programs, procedures, and associated documentation as well as data required for the operation of a system.

(ISO/IEC 2382:2015)

Software is a computer program in any form, including those embedded in hardware

(EU Directive 2009/24/EC)

Disclaimer

This presentation is crafted based on the information accessible up to this date and is prepared with our utmost knowledge.

It reflects our own interpretation of the requirements demonstrated.

This presentation relies on the information currently available. The insights provided during this presentation and by the speaker should not be considered as consultancy or as a specific recommendation for action.

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

Official Journal of the European Union — EN L series

2024/1689 — 12.7.2024

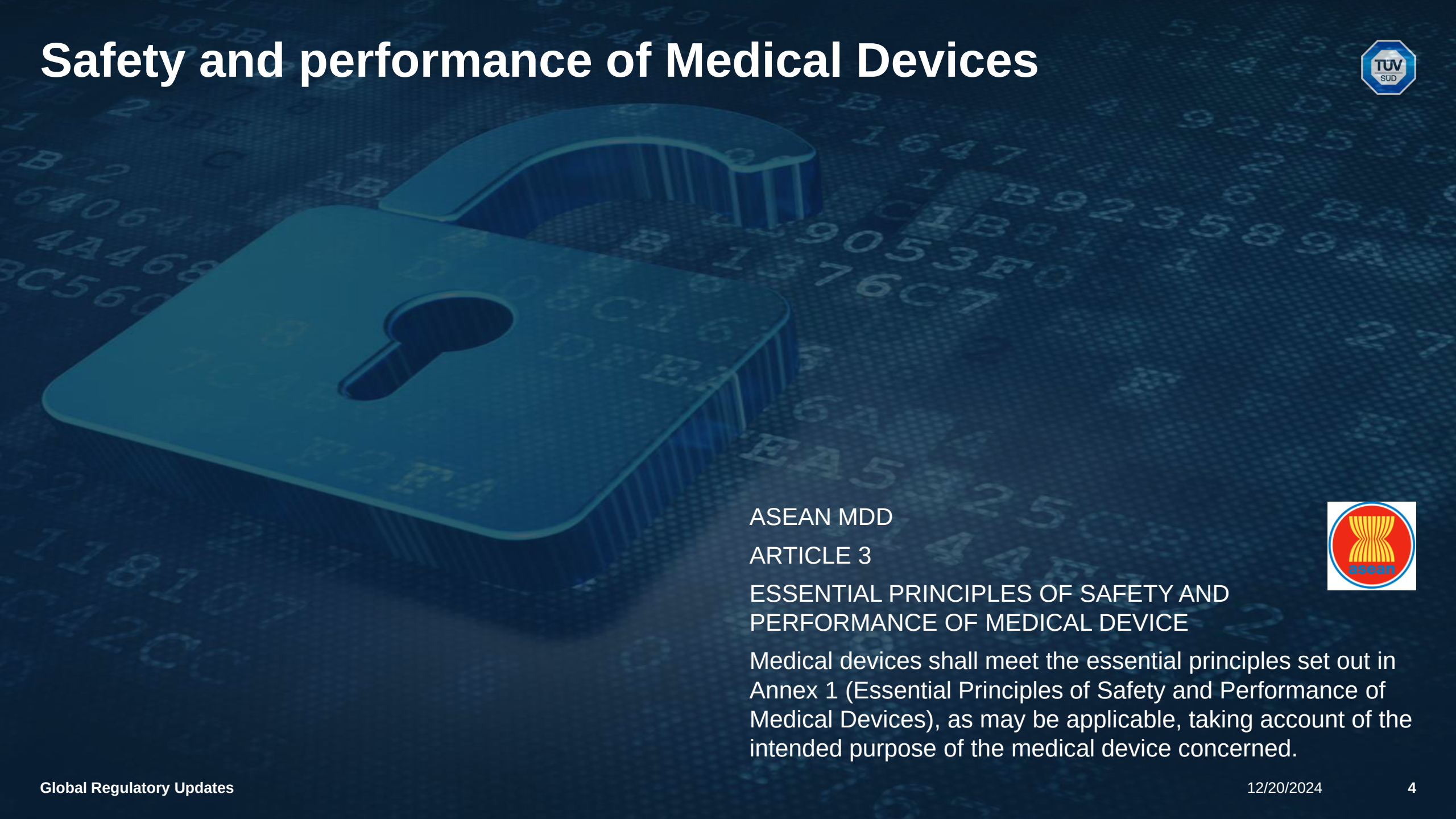
REGULATION (EU) 2024/1689 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 June 2024

laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)

These slides belong to TÜV SÜD PSB Pte Ltd, distribution or copying only allowed with written agreement

Safety and performance of Medical Devices



ASEAN MDD

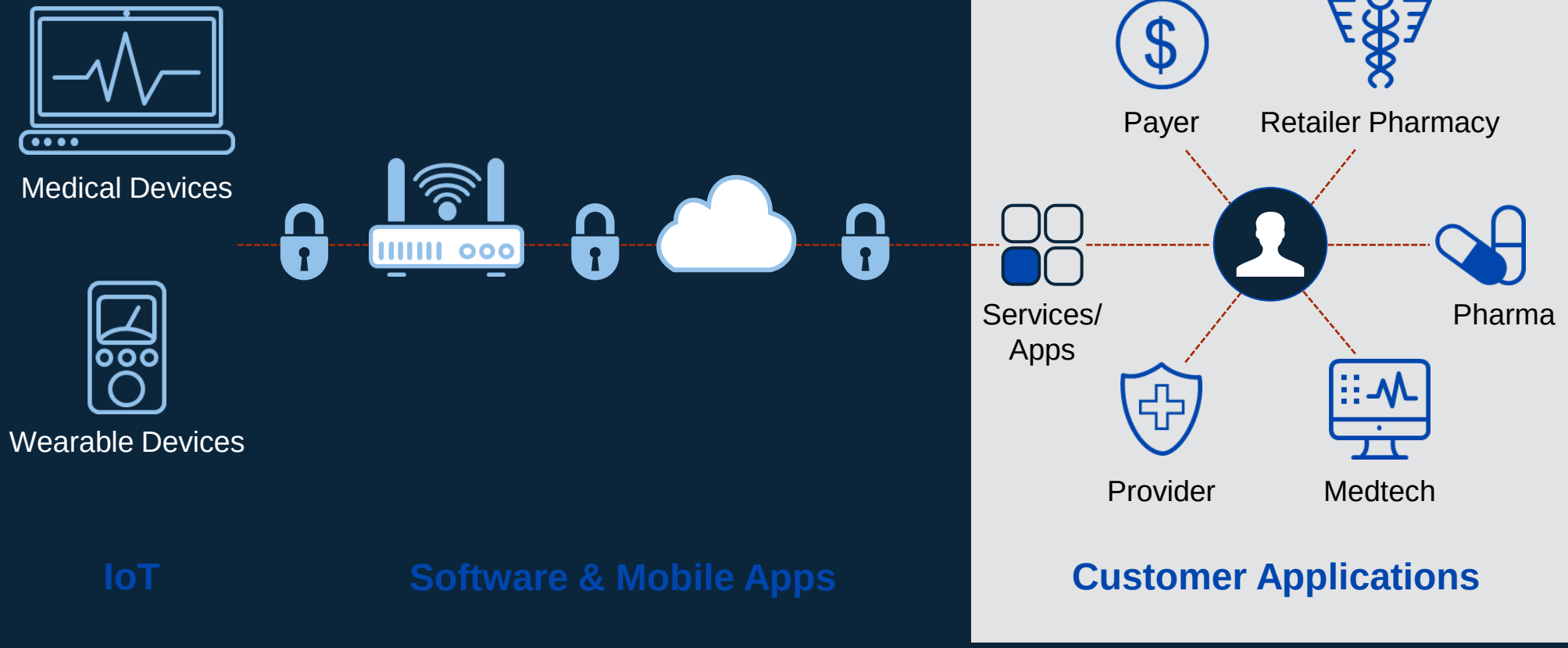
ARTICLE 3

ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICE

Medical devices shall meet the essential principles set out in Annex 1 (Essential Principles of Safety and Performance of Medical Devices), as may be applicable, taking account of the intended purpose of the medical device concerned.

Testing of Medical IoT Systems (Connected Ecosystem)

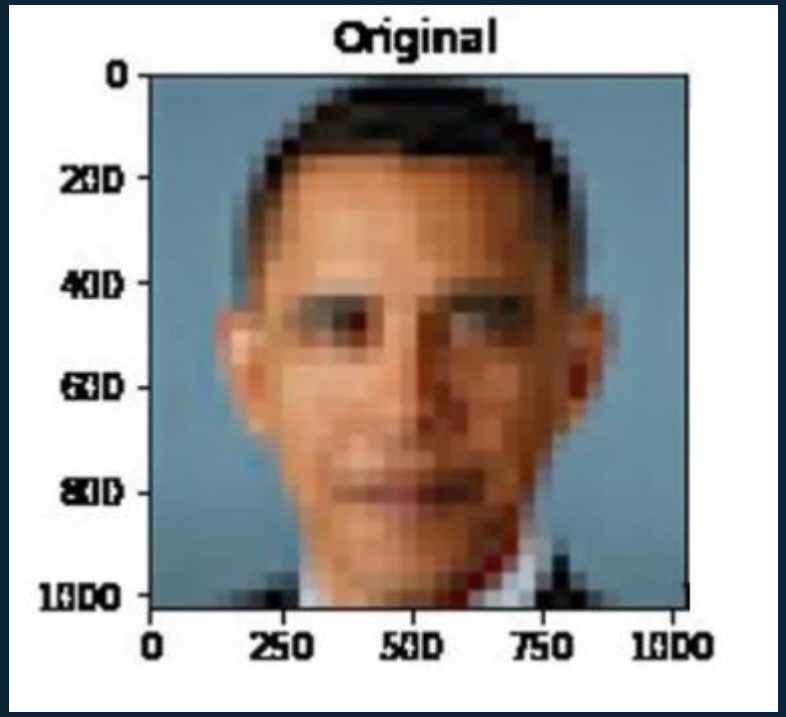
IoT System of medical devices



Including Safety, security and privacy across the different environments

Technological Risks

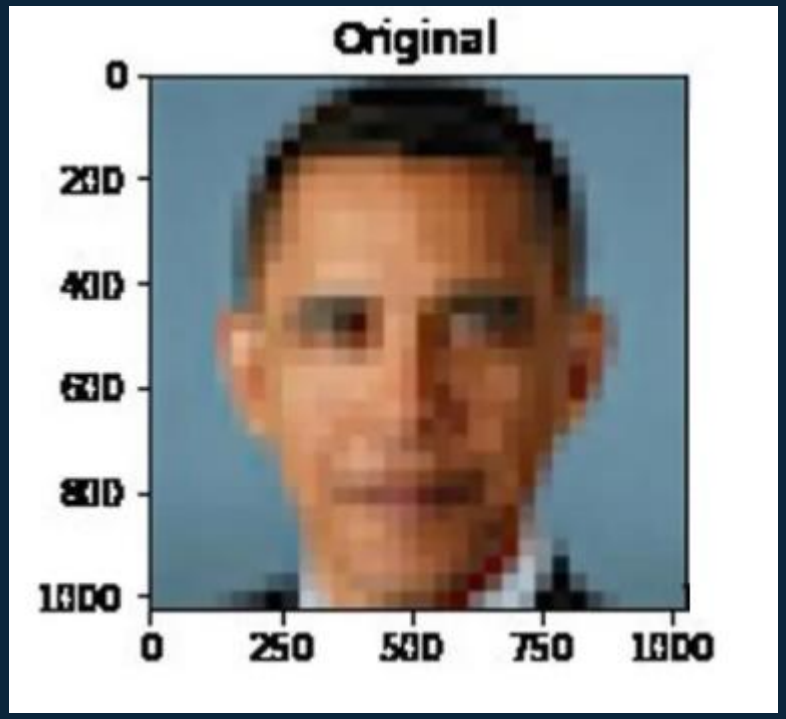
How to challenge risks with new technologies

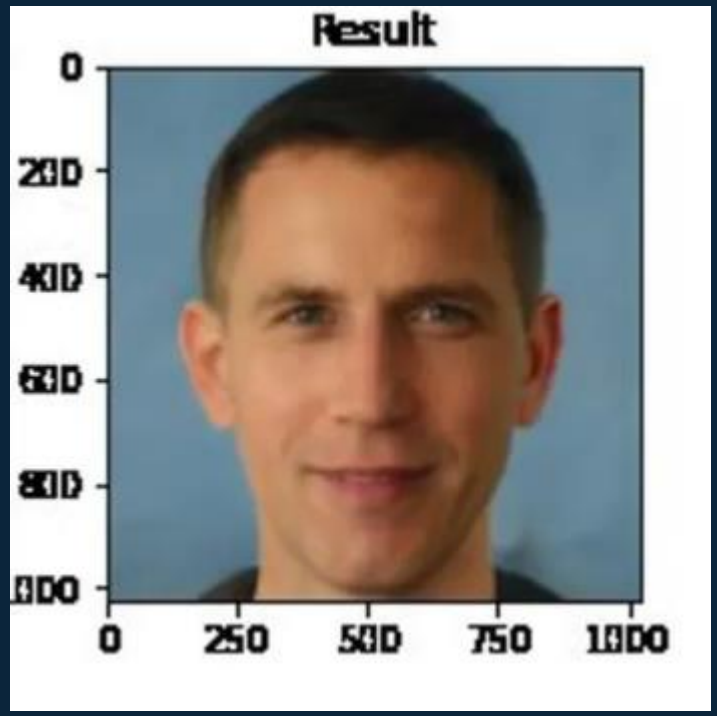


Source: @CHICKEN3GG/TWITTER

Technological Risks

How to challenge risks with new technologies





Source: @CHICKEN3GG/TWITTER

Artificial Intelligence (AI) Act - 2024/1689

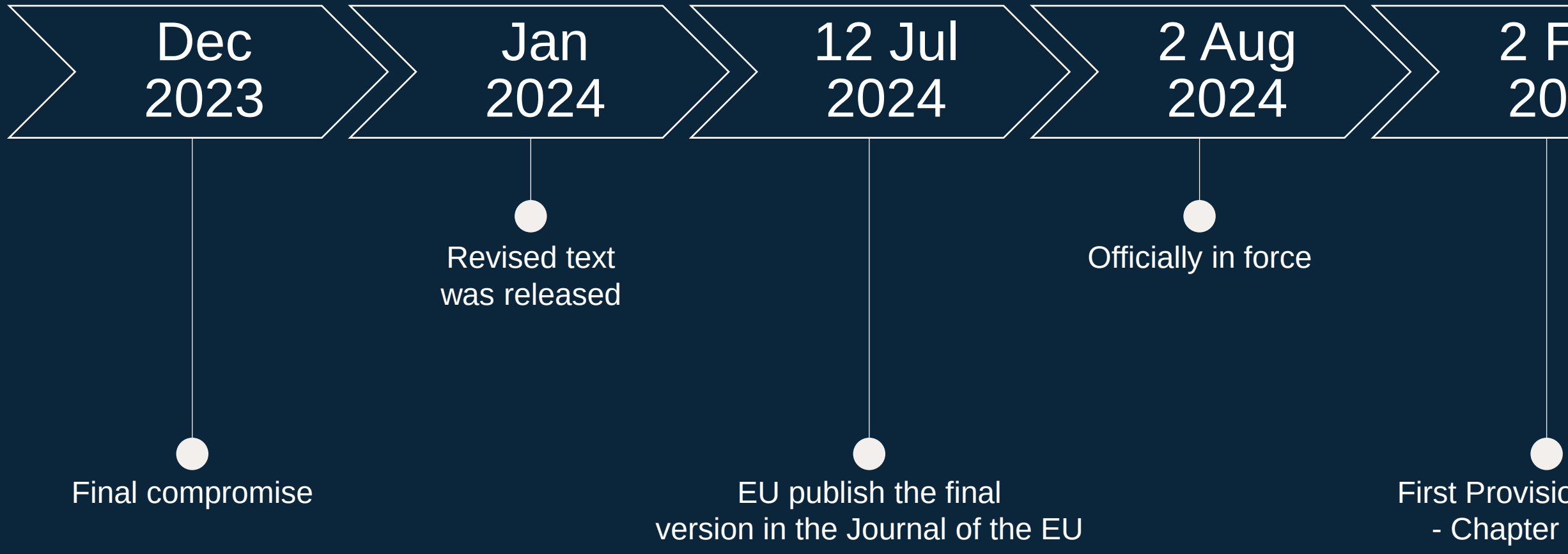
Article 3

(1)

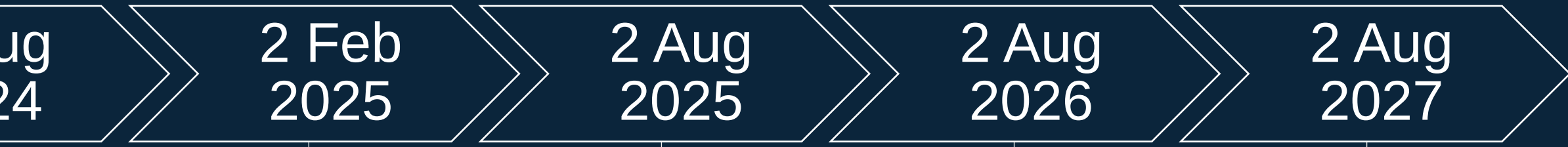
‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments.

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401689

Timeline


Dec 2023
Jan 2024
12 Jul 2024
2 Aug 2024
2 F 20
Final compromise
Revised text was released
EU publish the final version in the Journal of the EU
Officially in force
First Provisio - Chapter

Timeline



force

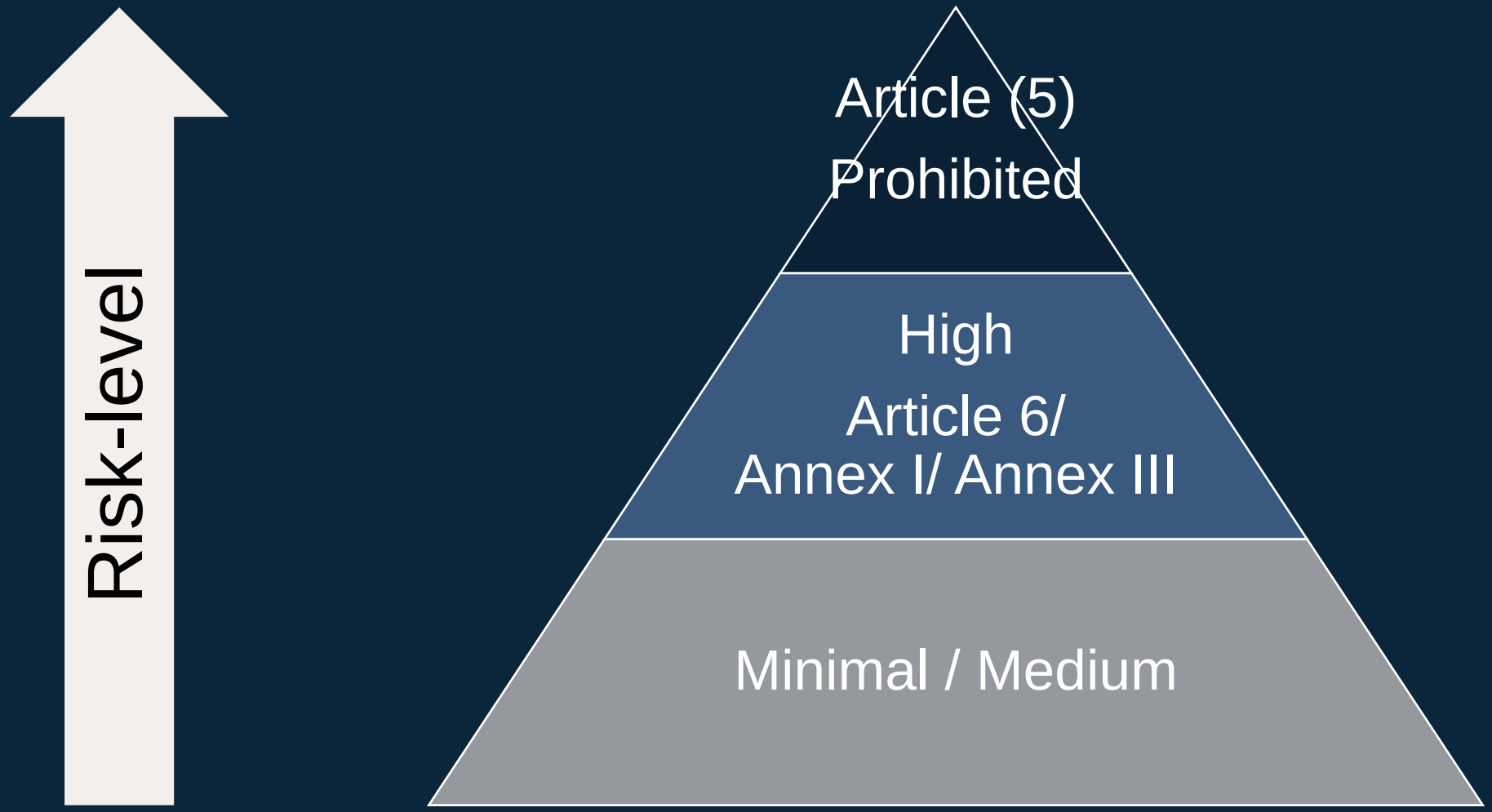
First Provisions apply:
- Chapter I and II

Chapter III Section 4,
Chapter V,
Chapter VII and Chapter XII and Article 7
Exception: Article 101

Full application except…

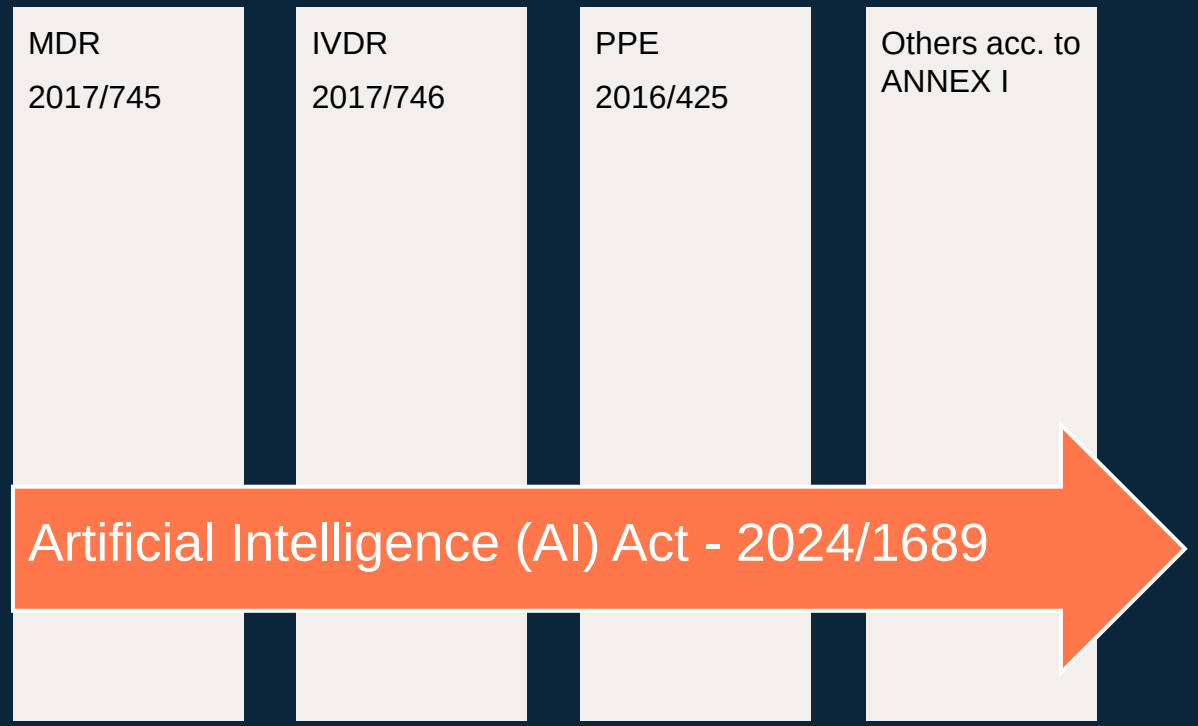
Article 6(1) and the corresponding obligations

What does the AI Act regulate



What does the AI Act regulate

Horizontal legislation



- Artificial intelligence Software acc. specification
- Categorization in risk of use
- Prohibited AI included
- Penalty up to 7% of worldwide annual turnover

Thank you

For more information / enquiry, please visit our websites at:

Visit our websites:	
Singapore, Australia & New Zealand: www.tuvsud.com/sg	**Malaysia:** www.tuvsud.com/my
Indonesia: www.tuvsud.com/id	**Thailand**: www.tuvsud.com/th
Philippines: www.tuvsud.com/ph	**Vietnam**: www.tuvsud.com/vn