



MIC MRA Workshop

Cybersecurity in the current situation in Europe

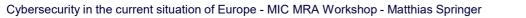
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Cybersecurity in the current situation in Europe

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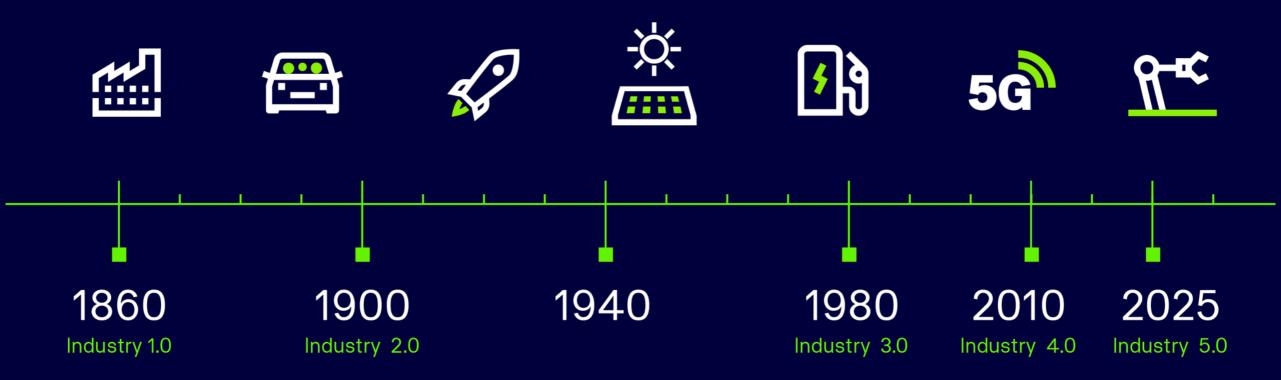
TÜV NORD CERT GmbH, Essen, Germany





Keeping People and technology safe

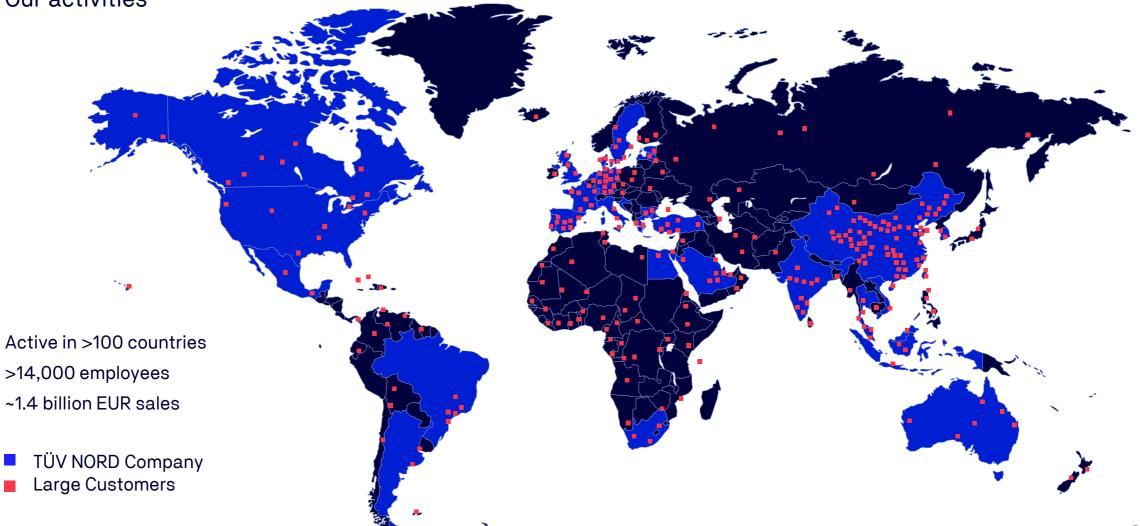
For more than 150 years. Every day, worldwide





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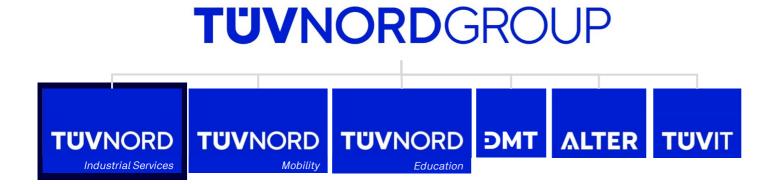
Our activities





TÜV NORD GROUP

TÜV NORD GROUP is among the leading global technology service provider delivering TICCET services



Core Services:

- Testing
- Inspection
- Certification
- Consulting
- Engineering
- Training

Business Units

- Industrial Services
- Mobility
- Engineering & Natural Resources
- Aerospace
- Training
- Information Technology









Actual Security Regulations

Already in force

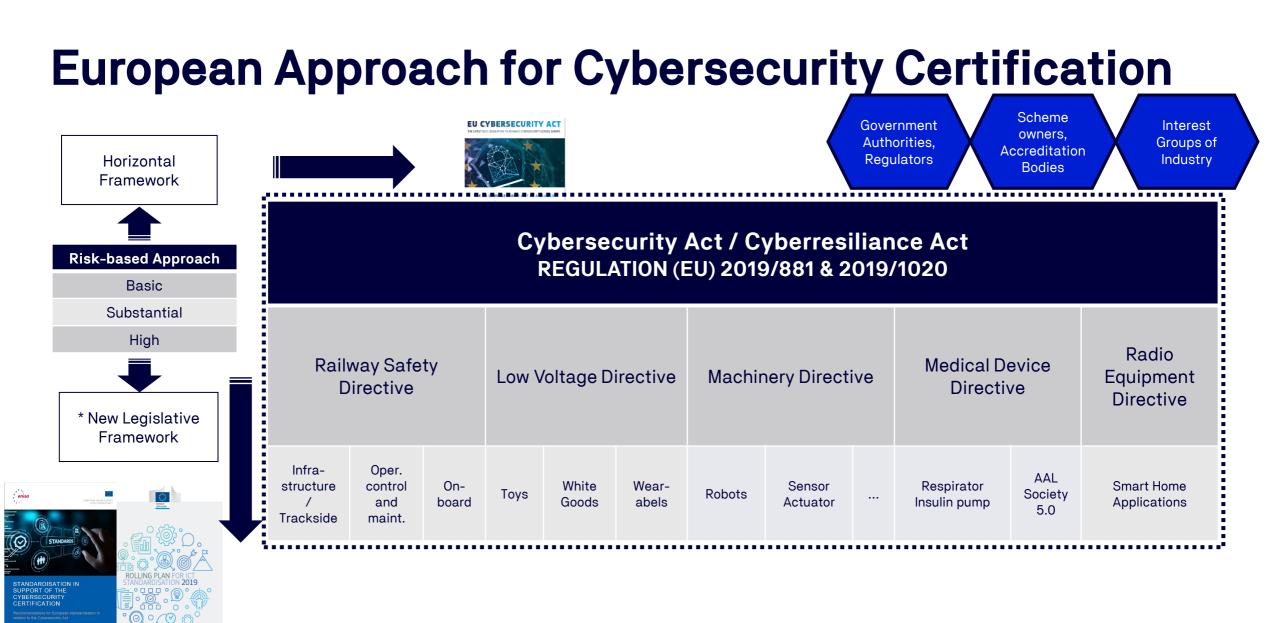
- GDPR (General Data Protection Regulation)
 - Privacy by design & default / security by design
- NIS 2 (Network Information Security)
- Providers of Essential Services (Critical Infrastructure)
- Digital Services Providers
- → NESAS CCS-GI for 5G
- Cyber Security Act / Cyber Resilience Act
 - Framework and Development of the European Certification Schemes
 - IoT, IIoT
 - Consumer Goods
 - 5G, Cloud Services
- MDR (Medical Device Directive)
 - CE Marking for Medical Devices
- RED (Radio Equipment Directive)
 - CE marking for products with radio (GSM, WiFi, Bluetooth etc.)

Vertical Specific Directives and Regulations

- General Product Safety Directive 2001/95/EC
- Safety & Security under all product regulations
- Low Voltage Directive 2014/35/EC
 - CE marking for electrical equipment
- Machinery Regulation 2023/1230/EC
 - CE marking for machinery equipment







* product harmonization legislation in line with Decision 768/2008/EC



European Legislative Approach



New Machinery Regulation

	EUROPEAN COMMISSION				
	Proposal for a				
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL					
on machinery products					

In a digital market driven by the Internet of Things and AI powered systems, <u>vulnerability to cyberattacks of factories and</u> <u>critical infrastructures is a de facto concern and a growing threat</u>. For example, some industrial processes nowadays are conveniently managed through mobile apps. While such remote controls might increase production's efficiency, they also create targets for cyber-attacks. This means that cybersecurity has a direct impact on workplace safety, and that the cybersecurity of industrial control systems and networks has therefore become a prerequisite. **Consideration to the threats and vulnerabilities described above needs to be given as early as the design stage by employing "security by design" solutions.**

> Integration of Cyber Security in the new Machinery Regulation to ensure <u>Essential Health and Safety Requirements (</u>EHSR). Cyber Security is central element and mandatory for Machinery compliance.



Cyber Resilience Act

The Act will

- Ensure that products with digital elements placed on the EU market have fewer <u>vulnerabilities</u> and that
- <u>manufacturers remain responsible</u> for cybersecurity <u>throughout a product's life cycle;</u>
- Improve <u>transparency</u> on security of hardware and software products;
- Business users and consumers benefit from better protection
- Provide harmonised rules for the placing on the market of connected hardware and software products;

Timeline



Manufacturers will have to

\rightarrow report actively exploited vulnerabilities and incidents;

- → Once sold, manufacturers must ensure that for the expected product lifetime vulnerabilities are handled effectively;
- → Clear and understandable instructions for the use of products with digital elements;
- → Security updates to be made available for at least five years

• Economic operators and Member States will have two years to adapt to the new requirements. The obligation to report actively exploited vulnerabilities and incidents will apply after one year.



Cyber Resilience Act

Affected Products

- Differentiation between self assessment and third party assessment
- Criteria and examples for categories are to be fixed by delegated act
- Risk Analysis will be the basis for decision
- Third party assessment beneficial in case of uncertainty
- Self-assessment for safety critical components not possible

90% of products	10% of products			
Default category	Critical "Class I"	Critical "Class II"	Highly critical	
Self-assessment	Application of a standard or third party assessment	Third party assessment	Mandatory EU certification	
Criteria: n/a	 Crite Functionality (e.g. critical Intended use (e.g. industri Other criteria (e.g. extent 	 Additional criteria: Used by NIS2 entities Resilience of supply chain 		
European Commission	To be amended/specified via delegated acts			
Examples:	Examples (Annex III):	Examples (Annex III):	Examples:	
Photo editing, word processing, smart speakers, hard drives, games etc.	Password managers, network interfaces, firewalls, microcontrollers etc.	Operating systems, industrial firewalls, CPUs, secure elements etc.	n/a (empowerment to future-proof the CRA)	

Figure – courtesy from European Commission





Cyber Resilience Act

<u>Take-aways</u>

- All Product manufacturers of connected devices affected
- CE-conformity <u>includes</u> Cybersecurity
- Machine Regulation conformity does not show implicitly CRA conformity
- Generic CRA obligations are covered by IEC 62443-4-1

- Foreseen harmonized standards for presumption of conformity:
 - -IEC 62443-4-1 & -4-2
 - ETSI EN 303 645 [or similar]
 - -ISO/IEC 15408

Generic CRA requirements

\rightarrow report actively exploited vulnerabilities and incidents;

- → Once sold, manufacturers must ensure that for the expected product lifetime or for a period of five years (whichever is the shorter), vulnerabilities are handled effectively;
- Clear and understandable instructions for the use of products with digital elements;
- Security updates to be made available for at least five years

IEC 62443 compliance effects presumption of conformity with CRA and Machinery Regulation

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Radio Equipment Directive Delegated Act



Essential requirements of Article 3(3)

- d) radio equipment <u>does not harm the network or its</u> <u>functioning</u> nor misuse network resources, thereby causing an unacceptable degradation of service;
- e) radio equipment incorporates <u>safeguards</u> to ensure that <u>the personal data and privacy</u> of the user and of the subscriber are protected;
- f) radio equipment supports certain features ensuring protection from <u>fraud;</u>

Conformity assessment

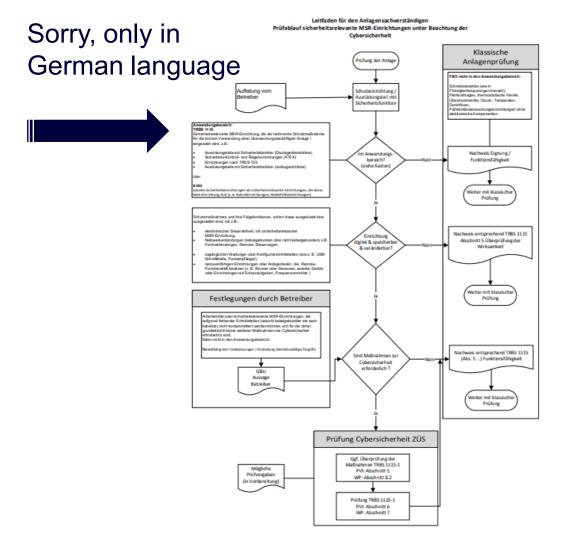
- Self-assessment
 - Using harmonised standards
- Third-party conformity assessment
 - In any case
 - Notified body to be involved
- Once performed:
 - Declaration of conformity
 - CE marking
 - Manufacturer becomes responsible to the MSA



Potential harmonized standards for presumption of conformity: EN 303 645 [or similar]



TRBS 1115-1 : Cybersecurity for Operators

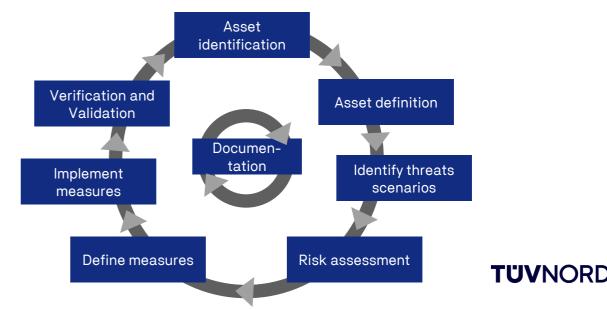


Compliance Requirements

Section 3: **Risk assessment** - assess threats and derive measures Section 4: **Implementation** of the measures Section 5: **Verification** of the effectiveness of the measures before first use Section 6 +7: **Testing** the work equipment / system requiring

monitoring

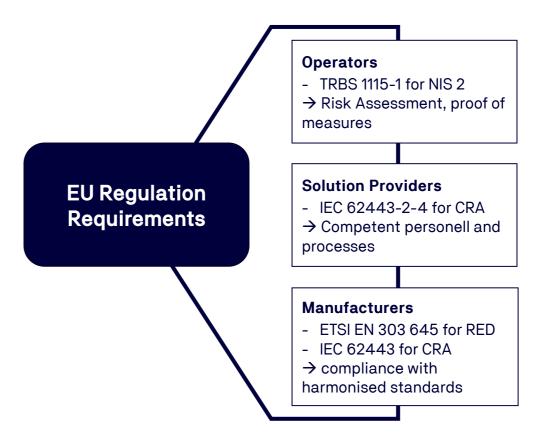
Section 8.2: Regular checks of functionality





European Cybersecurity Regulation

- NIS 2, CRA, RED most affecting Cyber Regulations in EU
- Mandatory requirements to place products in EU market
- Top down regulation for all logical layers (Operators, Solution Provider and Product Manufacturers)
- Integration of requirements in vertical directives/regulations (e.g. Machine Reg., MDR)
- IEC 62443 series and ETSI EN 303 645 as main standards for presumption of conformity



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Questions?

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