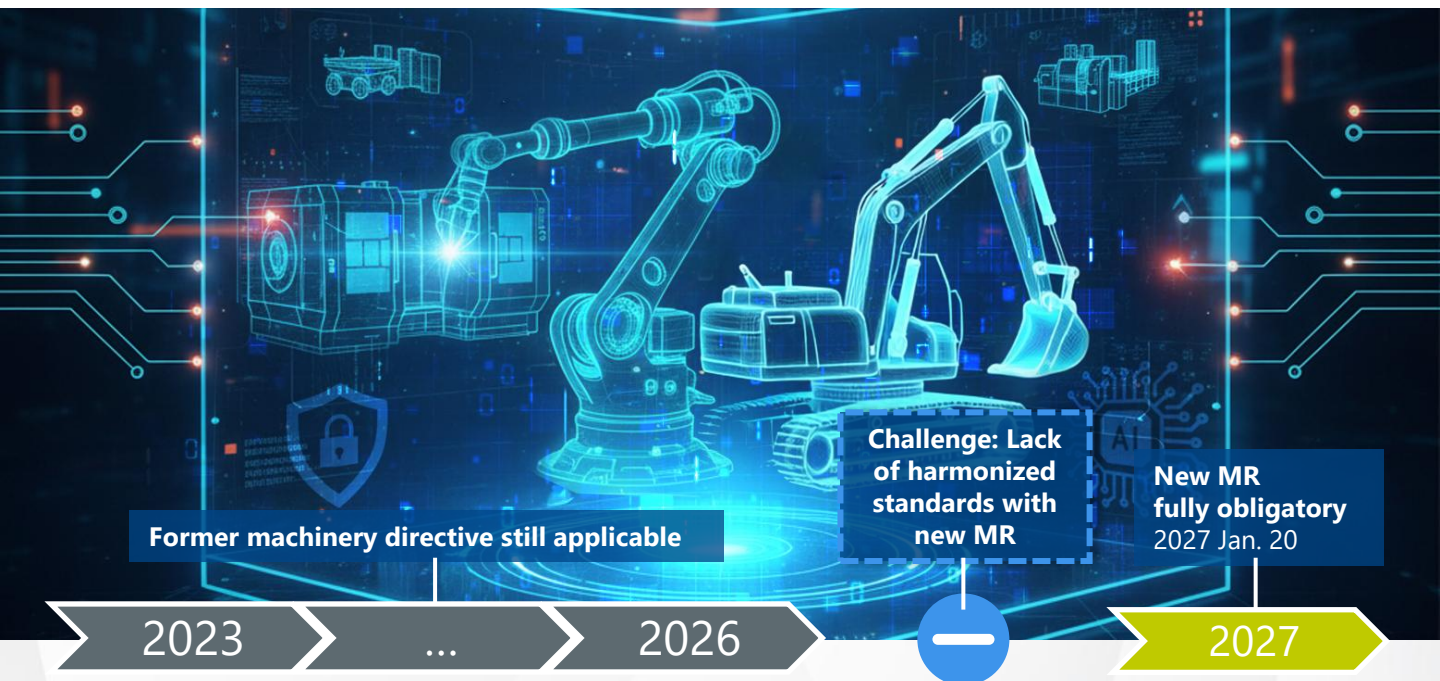


THE NEW EU MACHINERY REGULATION (MR)

New mandatory requirements for CE compliance



Major changes compared to former Machinery Directive



Scope Extension: Software-only Products

NEW: Software ensuring safety functions is now officially classified considered as a safety component in Annex II. As a result, CE marking and declaration of conformity are mandatory.

Is your product now subject to CE marking requirements?



AI & Machine Learning

NEW: Explicit obligations for "control systems [...] with [...] self-evolving behaviour"

When used in safety functions, these products are classified as "high-risk" machinery (Annex I, part A). Related publication: ISO/IEC TR 5469

Are you using, or planning to use, AI/ML in machinery safety functions?



Protection against Corruption

NEW: Cyber Security obligations:

- Risk assessment req.
- Protection of safety-critical software/data against attackers
- Logging requirements

To-be-harmonized standard: EN 50742

What does this mean for you?
→ Find out on page 2.

Further changes

- Changes in conformity assessment procedures (modules A to H)
- Documentation in digital format (user instructions, declaration of conformity)
- Changes in scope (e.g., E-Bikes, E-Scooter now in scope)
- Changed definitions and obligations for "Economic operators"
- Refined obligations in case of "substantial modification"

ITK's MACHINERY REGULATION SERVICES

From SMEs to large companies: We find individually tailored solutions that strike the perfect balance between pragmatism, efficiency, structured execution, and consistent results.

SAFETY SERVICES FOR THE MACHINERY REGULATION (MR)



Maturity Check

Based on the applicable extend of the new MR and harmonized standards



CE-Consulting

Expert support during the whole product lifecycle and consulting how to deal with lacking harmonized standards for your product



Risk Assessment and Management

Tool-assisted, based on ISO 12100, covering the extended scope of the new MR



Safety Concepts and Analysis

Developing safety concepts for your product, e.g., based on ISO 13849 and conducting appropriate Safety Analyses (e.g., FMEA)



Safety Software Development

Process-compliant software development (e.g., according to ISO 13849, IEC 61508), also for safety-relevant SW-only products



Training & Coaching

Customized training courses or coaching services for machinery safety and related standards, including AI-based safety functions

CYBER SECURITY SERVICES TO ENSURE „PROTECTION AGAINST CORRUPTION“



Risk assessments

Determine the „adequate level“ of protection against corruption for a given product.



Cyber security development

Have experts help you with cyber security technologies (e.g. cryptography, secure boot, secure updates, etc.).



Cyber security concepts

Selection of appropriate counter-measures & evidence collection of modifications/interventions.

More CE-relevant Cyber Security regulations:

Protection against corruption

EU Mach. Reg. EU CRA



Please check our services for the EU CRA!

CONTACT US:

FunctionalSafety@itk-engineering.de

FuSi @ ITK:



Security @ ITK:



ITK Engineering GmbH
Headquarters Ruelzheim
Im Speyerer Tal 6
76761 Rülzheim, Germany

Tel.: +49 (0)72727703-0
info@itk-engineering.de
www.itk-engineering.com

Follow us on:

