Welcome to Machinery Safety Webinar
The Machinery Regulation

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PILZ
THE SPIRIT OF SAFETY

Welcome

- Your presenter is Jamie Thomas
- You can type questions using the tool bar to the right side of your screen, my co-hosts Alex Bryce and Rhiannon Gibson will answer these during the course of the webinar
- The webinar is being recorded, a link to the recording will be sent to all regsistrants shortly after the webinar has concluded.
- The slides are available for up on request via the questions function

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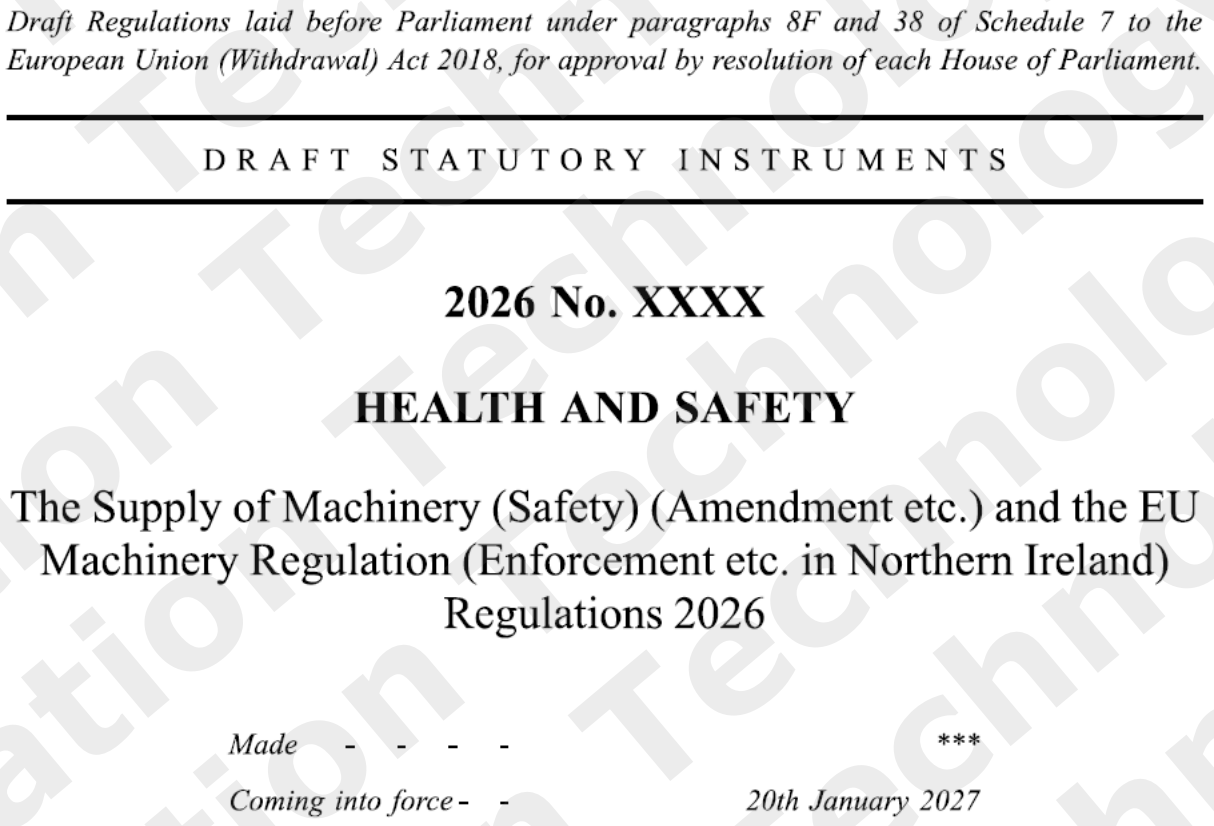
The Machinery Regulation 2023/1230

UK Supply of Machinery (Safety) Regulation - Update

- **1 June 2026:** The UK government officially laid the draft Statutory Instrument—the *Supply of Machinery (Safety) (Amendment etc.) and the EU Machinery Regulation (Enforcement etc. in Northern Ireland) Regulations 2026*—before Parliament for approval
- **20 January 2027:** This is the exact date the regulations officially **come into force** across England, Scotland, Wales, and Northern Ireland. It perfectly aligns with the EU enforcement date for EU Machinery Regulation
- **There is no transition or grace period after January 2027**



Draft Regulations laid before Parliament under paragraphs 8F and 38 of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2026 No. XXXX

HEALTH AND SAFETY

The Supply of Machinery (Safety) (Amendment etc.) and the EU Machinery Regulation (Enforcement etc. in Northern Ireland) Regulations 2026

Made - - - - ***

Coming into force - - *20th January 2027*

A statutory instrument (SI) is a form of secondary (or delegated) legislation used in the UK to bring into force, alter, or update the provisions of an Act of Parliament. It allows the law to be modified without Parliament having to pass a completely new Act.

Introduction to CE Marking

What is CE Marking ?

- Definition:
  - “It means a marking by which the manufacturer indicates that machinery or a related product is in conformity with the applicable requirements set out in Union harmonisation providing for its affixing.”
- A physical declaration by the manufacturer that the product complies with all applicable EU directives and Regulations.
- The product can be legally placed on the market
- “Passport” for free movements across the EEA
- A symbol that should indicate a safe product
- To ensure high level of safety and identical safety requirements for machinery in every country

Learn more about CE Marking

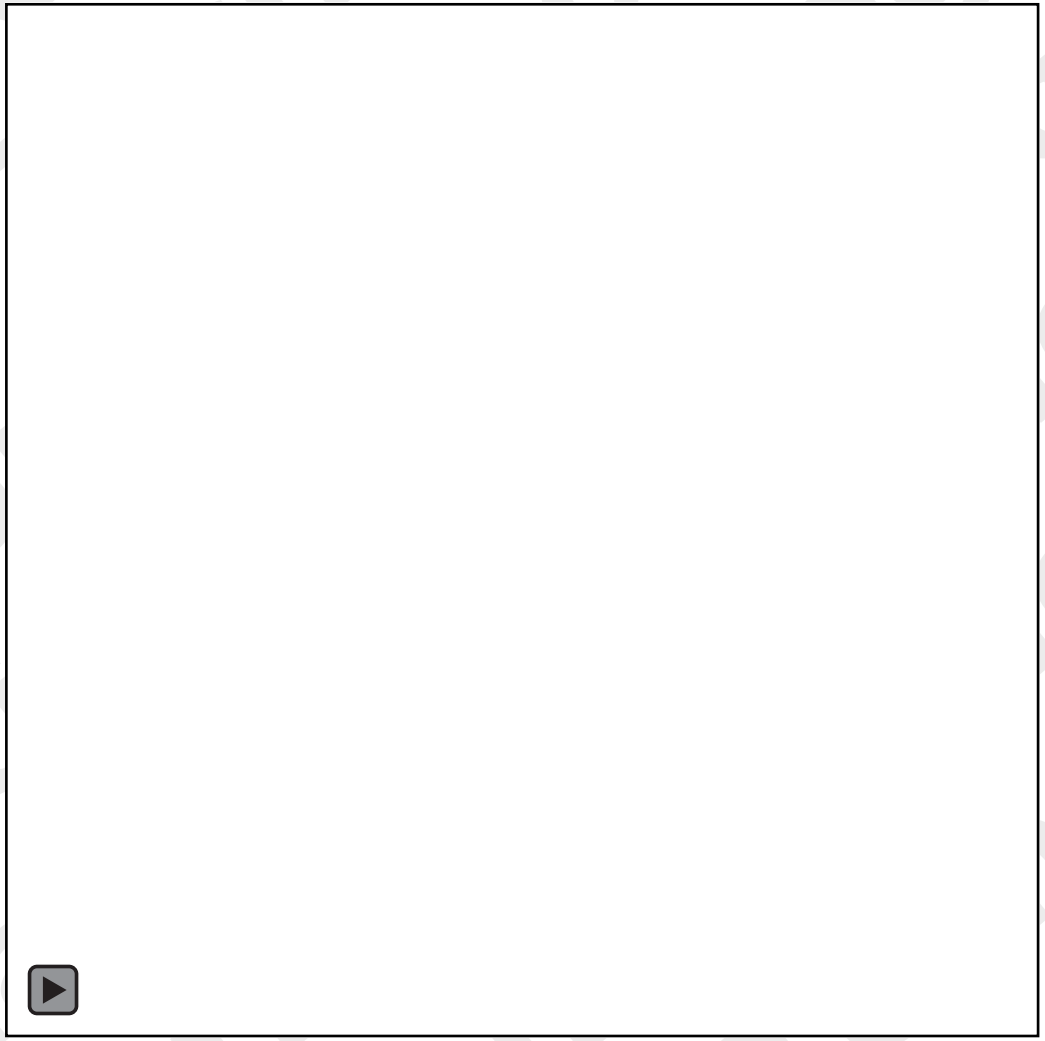
1.1

Introduction Machinery Regulation and Timeline

Publication of the new Machinery Regulation 2023/1230

Basic information

- **Successor to the Machinery Directive 2006/42/EC**
- **Publication in the EU Official Journal**
  - 29th June 2023
- **Validity starts on 20th January 2027**
  - No national transposing legislation required !
  - UK situation open
    (mutual acceptance of CE – UKCA Mark)



Learn more about the Machinery Regulation

Introduction to Machinery Regulation

Structure of the Machinery Regulation

Official Source for regulation:

EUR-Lex - 32023R1230 - EN - EUR-Lex (europa.eu)

The MR is divided in three parts:

- **Recitals:**
  - Recitals introduce the main provisions of the directive and present the reasons for their adoption. Recitals do not have legal force as such and do not usually figure in national legislation implementing the regulation
- **Articles:**
  - Articles of the MR detail the administrative requirements for the application of the regulation
- **Annexes:**
  - The 12 annexes of the MR contain practical requirements for the construction and documentation of the products within the machinery regulation scope

Introduction to Machinery Regulation

Structure of the Machinery Regulation

Recitals

Chapter I	Chapter II	Chapter III	Chapter IV and V	Chapter VI to VIII	Chapter IX
General provisions and freedom of movement	**Obligations of economic operators**	**Conformity of products within the scope of MR**	**Conformity assessment and Notifying authorities**	**Surveillance, committee procedure and penalties**	**Transitional and final provisions**
Articles 1 - 9	Articles 10 - 19	Articles 20 - 24	Articles 25- 42	Articles 43 - 50	Articles 51 - 54

- **ANNEX I** – Categories of machinery or related products to which follow special procedures
- **ANNEX II** – Indicative list of safety components
- **ANNEX III** – Essential safety requirements relating to the design and construction
- **ANNEX IV** – Technical documentation
- **ANNEX V** – EU declaration of conformity and EU declaration of incorporation
- **ANNEX VI** – Internal production control (Module A)
- **ANNEX VII** – EU type-examination (Module B)
- **ANNEX VIII** – Conformity to type based on internal production control (Module C)
- **ANNEX IX** – Conformity based on full quality assurance (Module H)
- **ANNEX X** – Conformity based on unit verification (Module G)
- **ANNEX XI** – Assembly instructions for partly completed machinery
- **ANNEX XII** – Correlation table

Introduction to Machinery Regulation

Overview of Changes

EU Machinery Directive (2006/42/EC)	Subject	EU Machinery Regulation (2023/1230)
63	# of pages	102
30	# of Introductory remarks	86
29	# of articles	54
12	# of Annexes	12
Annex I	Essential Health & Safety Requirements	Annex III
Annex II	Declarations	Annex V
Annex III, XI	CE Marking, Notified bodies	See Articles and Reg 765/2008
Annex IV	Machine Categories	Annex I, Part A&B
Annex V	Safety Components	Annex II
Annex VI	Assembly Instructions	Annex XI
Annex VII	Technical Documentation	Annex IV
Annex VIII, IX, X	Conformity assessment procedures	Annex VI, VII, VIII, IX, X

Introduction to Machinery Regulation

Reasons and Objectives to change from Machinery Directive to Regulation

No.	Problem	
1	Divergences in interpretation due to transposition for a local legislation	Organisatoinal
2	Inconsistencies with other pieces of Union product safety legislation *	
3	Lack of clarity on the scope and definitions and possible safety gaps in traditional technologies	
4	Insufficient provisions for high-risk machines	
5	The Machinery Directive does not sufficiently cover new risks originating from emerging technologies	Technical
6	Monetary and environmental costs due to extensive paper-based documentation	

* New Legislative Framework (NLF) a framework of general principles and rules, which aims to make legislation on the Single Market for Goods clearer, more consistent and more effective. Adopted 2008

Publication of the new Machinery Regulation

The Directive is becoming a Regulation – what were the problems ? (and how they were addressed)

- **Problem 1**: The MD does not sufficiently cover new risks originating from emerging technologies
  → **Security & AI**
- **Problem 2**: Legal uncertainty due to a lack of clarity on the scope and definitions and possible safety gaps in traditional technologies
  → **Definitions of substantial modification & machines**
- **Problem 3**: Insufficient provisions for high-risk machines
  → **Segregation of high-risk machines into two groups/parts**
- **Problem 4**: Monetary and environmental costs due to extensive paper-based documentation
  → **Digital instructions**
- **Problem 5**: Inconsistencies with other pieces of Union product safety legislation
  → **Alignment to “New Legislative Framework“ (NLF)**
- **Problem 6**: Divergences in interpretation due to transposition
  → **Turning it into a Regulation**

Publication of the new Machinery Regulation

The Directive is becoming a Regulation – what does that mean?

- EU directives are valid in all EU member states, but must be transposed by the states into their national laws
- EU regulations must be applied verbatim as national laws in all EU member states
- There is no option of national/regional amendments in the interpretation
- The goal here is to reduce divergences in the interpretation of the MR in all member states

1.2

- Organisational changes

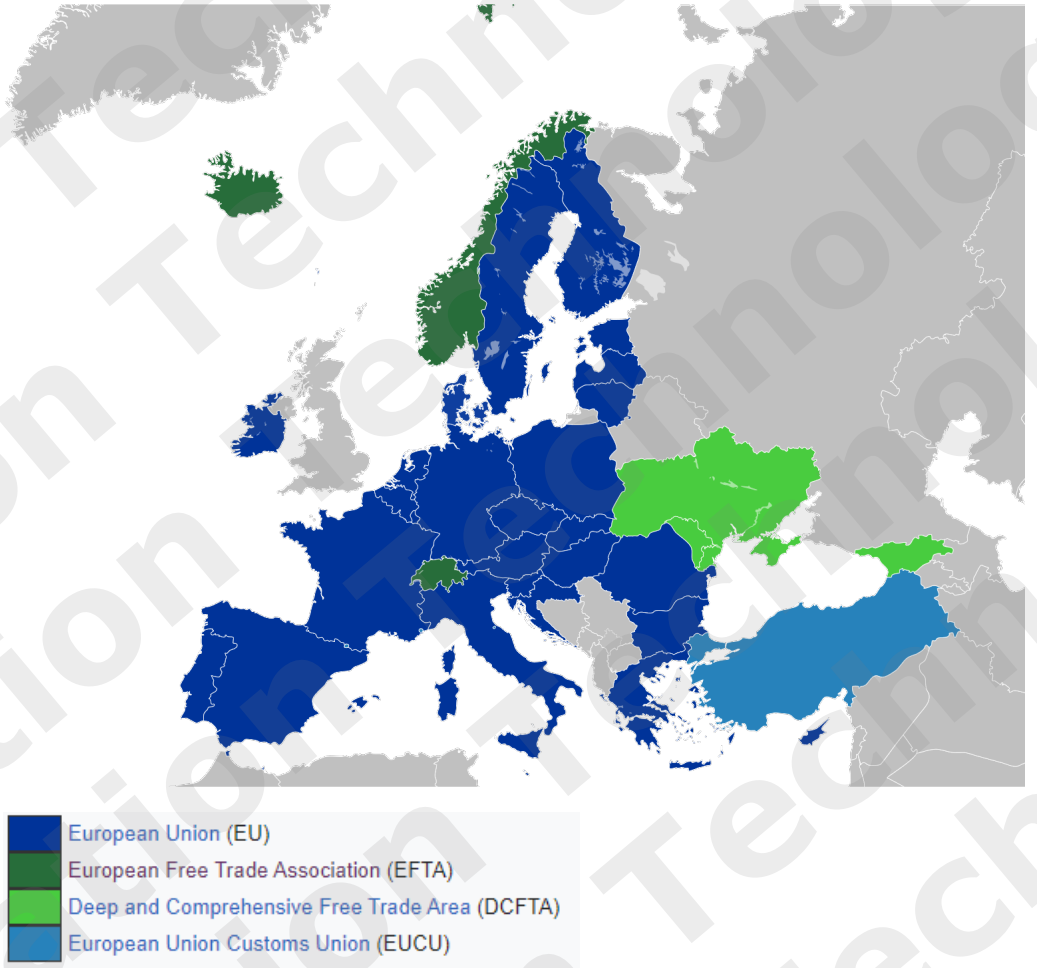
Organisational Changes

Transitional Period of Machinery Regulation

- Successor to the Machinery Directive 2006/42/EC
  - Final text published and available in all languages published by the EU Commission
  - Publication in the EU Official Journal 29.06.2023

EUR-Lex - 32023R1230 - EN - EUR-Lex (europa.eu

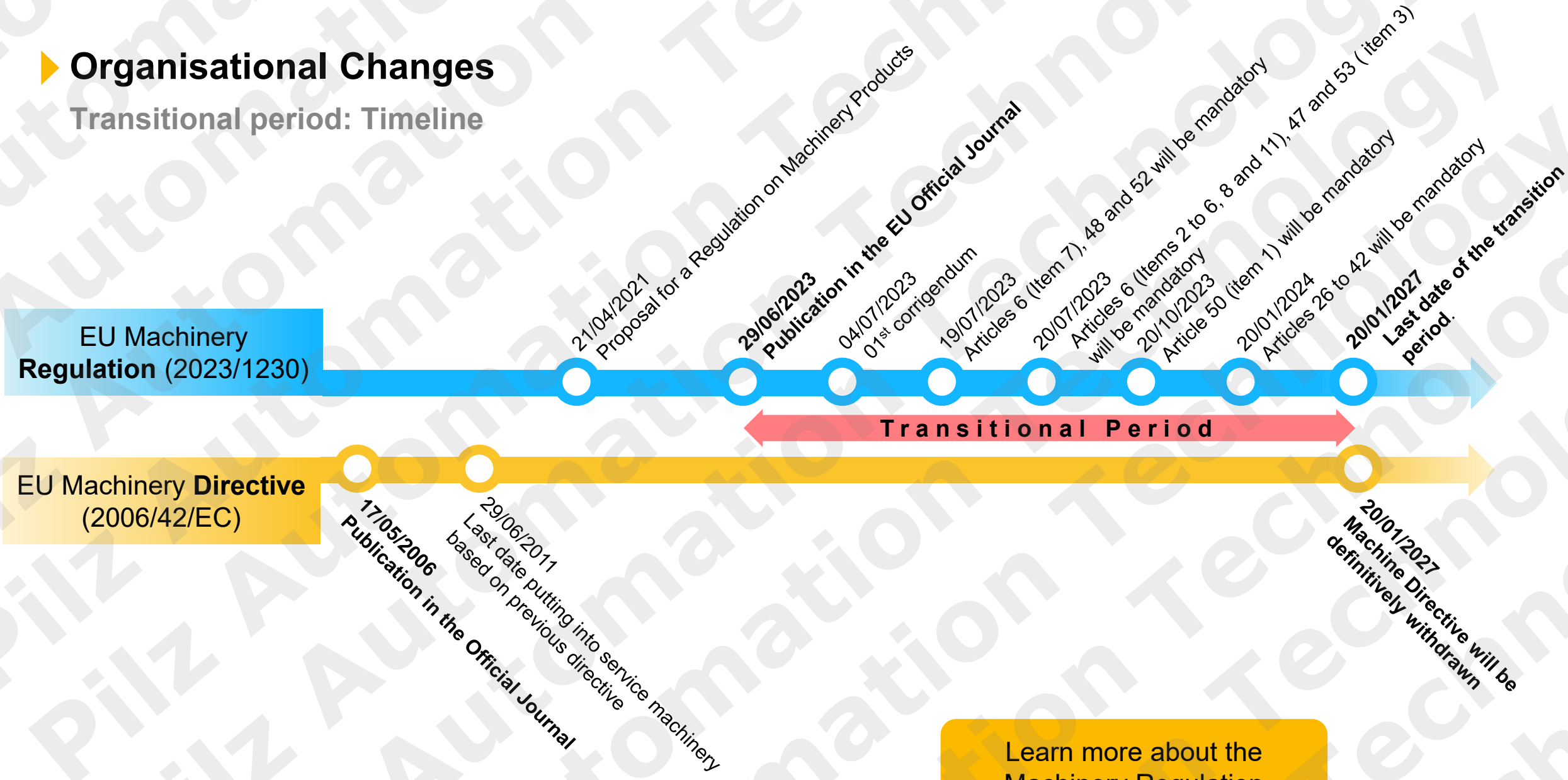
- Validity starts on January 20th, 2027
  - No national transposing legislation required! Regulations must be applied verbatim as national laws
  - UK also have UKCA legislation but also continues to accept the CE Mark.



Learn more about the Machinery Regulation

Organisational Changes

Transitional period: Timeline

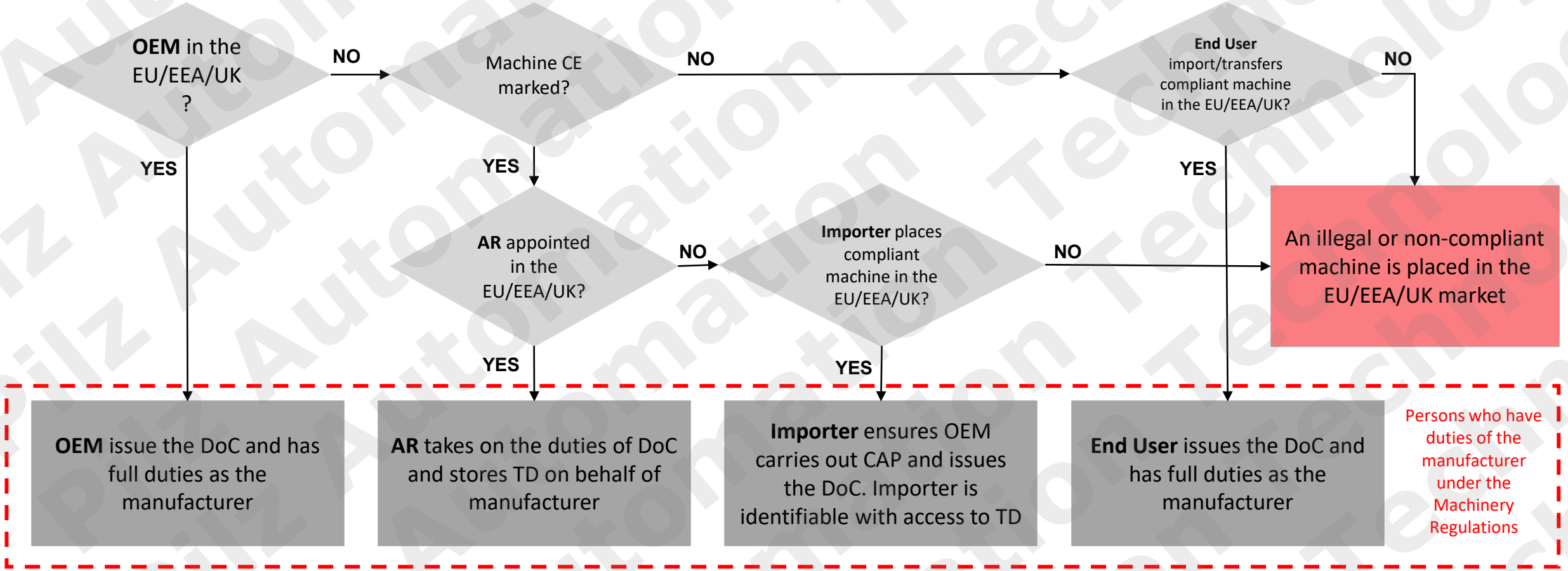


Learn more about the Machinery Regulation

Organisational Changes

Economic Operators: Persons who have duties as manufacturers under MR

Machine in scope of Machinery Regulation found on or at border of the EU/EEA/UK market

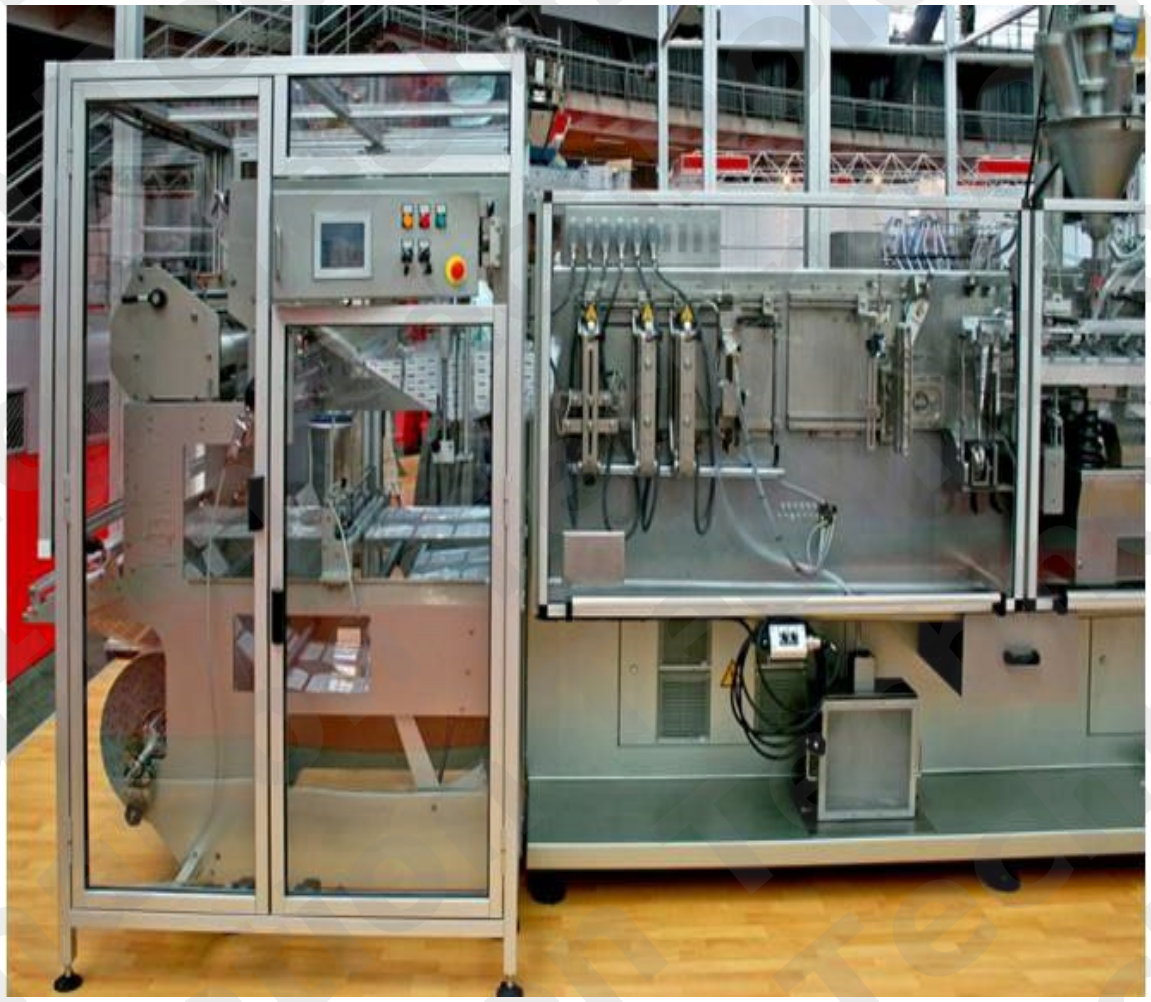


Organisational changes

Machinery Regulation - Terminology

“Machinery”

- Same as before
- Often mentioned together with “related products” which are also within the scope of this Regulation and include
  - Interchangeable equipment
  - Safety components
  - Lifting accessories, chains, ropes and webbing
  - Removable mechanical transmission devices



Organisational changes

Machinery Regulation: Scope

Definition (1): Machinery

- Assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application

Organisational changes

Machinery Regulation: Scope

New addition to MR

Definition (2): Machinery Assemblies

- Assembly missing only the components to connect it on site
  - Or to sources of energy and motion;
  - Or the uploading of the software intended for the specific application foreseen by the manufacturer.

Organisational changes

Machinery Regulation: Scope

Definition (3) : Mounted on Means of Transport

- An assembly ready to be installed and able to function as it stands only
  - If mounted on a means of transport
  - Or installed in a building or a structure

Definition (4) : Lifting Loads Manual Effort

- Assembly of linked parts or components, at least one of which moves, which are joined together intended for lifting loads, whose only power source is directly applied human effort so that they function as an integral whole

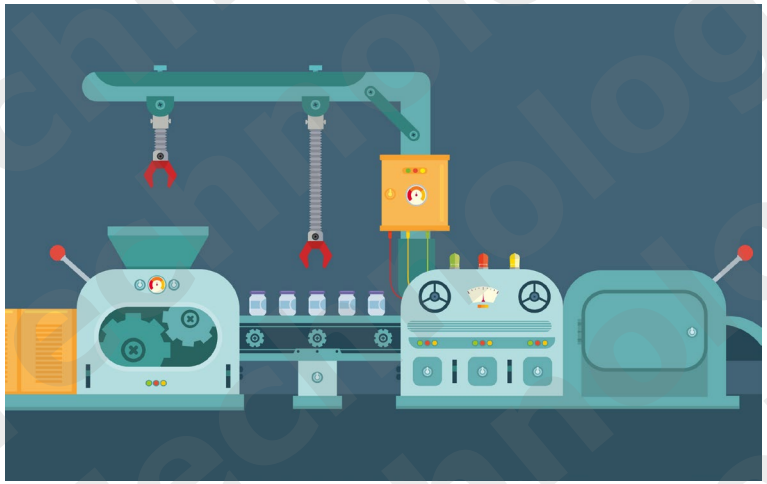
Organisational changes

Machinery Regulation: Scope

New addition to MR

Definition (5): Complex Assemblies

- Assemblies of machinery referred to in Definitions 1, 2 & 3 previously
- Which in order to achieve the same end are arranged and controlled so that they function as an integral whole.



New definition for Machinery (6)

- …an assembly as referred to in definitions 1 to 5 missing only the uploading of the software intended for the specific application foreseen by the manufacturer.”
- Example: CNC Milling Machine without the application software/configuration.

Organisational changes

Machinery Regulation: Scope

Definition: Partly Completed Machinery

- An assembly which is not yet machinery as it cannot in itself perform a specific application
- It is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming machinery
- A robot or a drive system is partly completed machinery

Organisational changes

Machinery Regulation: Scope

New addition to MR

Safety component means a physical or digital component

- Including software, of a product which is design or intended to fulfil a safety function, and
- The failure and/ or malfunction of which endangers the safety of persons, but

Annex II Provides a list of safety components

Safety functions means a function that serves

- To fulfil a protective measure designed to eliminate, or,
- If not possible, to reduce risk

Organisational changes

Machinery Regulation: Scope

New addition to MR

Definition: Making available on the market

- Any supply of a product within scope of this Regulation for distribution or
- Use on the Union market in the course of commercial activity;
- Whether in return for payment or free of charge.

Definition: Substantial modification

- A modification of machinery or related products, by physical or digital means
- To cater the safety of machinery after modification which requires,
  - Addition of guards or protective devices;
  - Modification of the existing safety control system;
  - The adoption of additional protective measures to ensure the stability or mechanical strength of that machinery.

Assess your machine modifications

Organisational changes

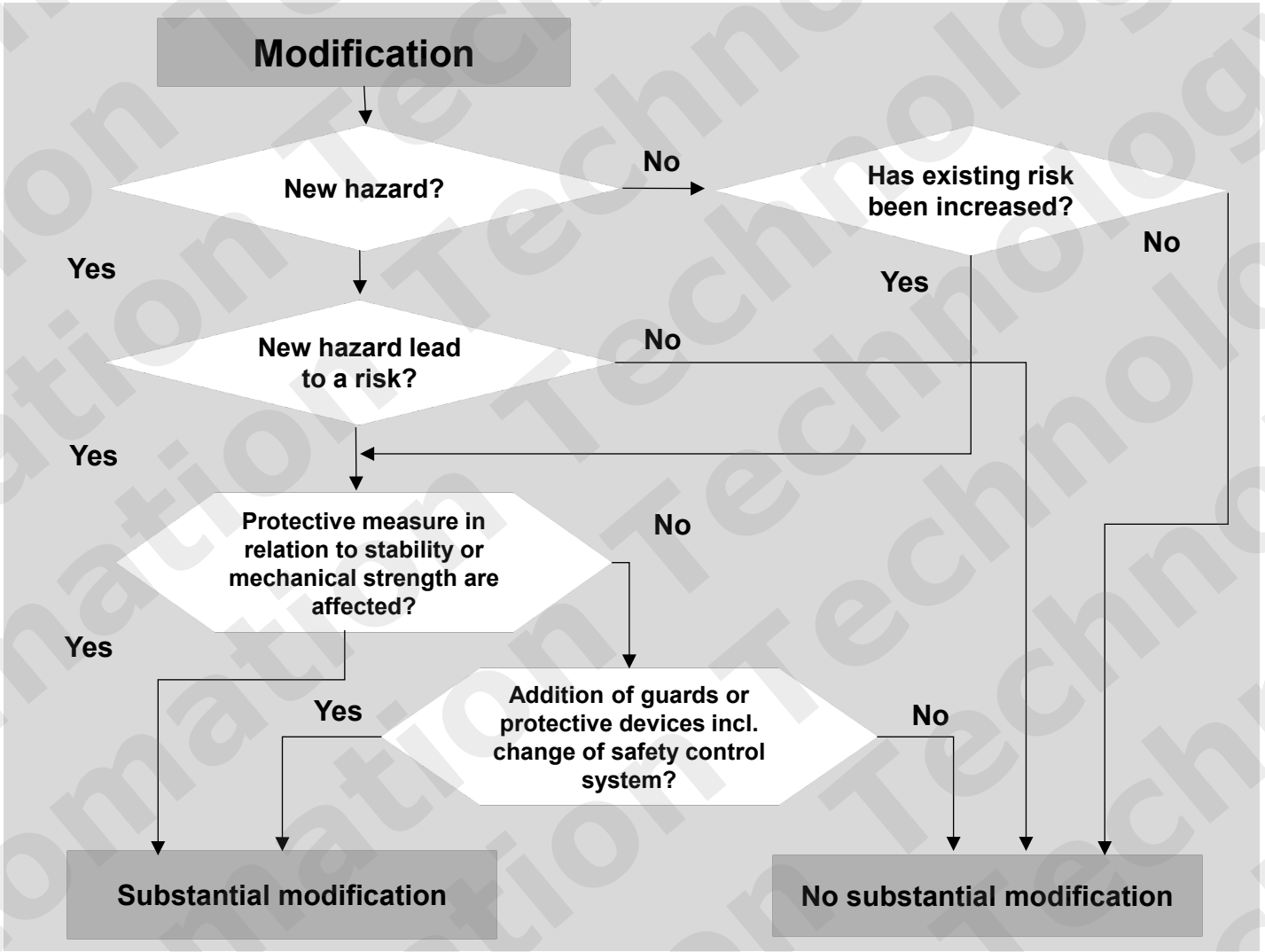
Scope: Substantial Modification

New addition to MR

- Modification of machinery may eventually mean a substantial modification if
  - new hazards or higher risks are created
  - the existing safety concept is not sufficient
  - substantial modification can be software driven

- Substantial modification means the design of a new machine. The existing documentation shall remain valid for the unmodified part.

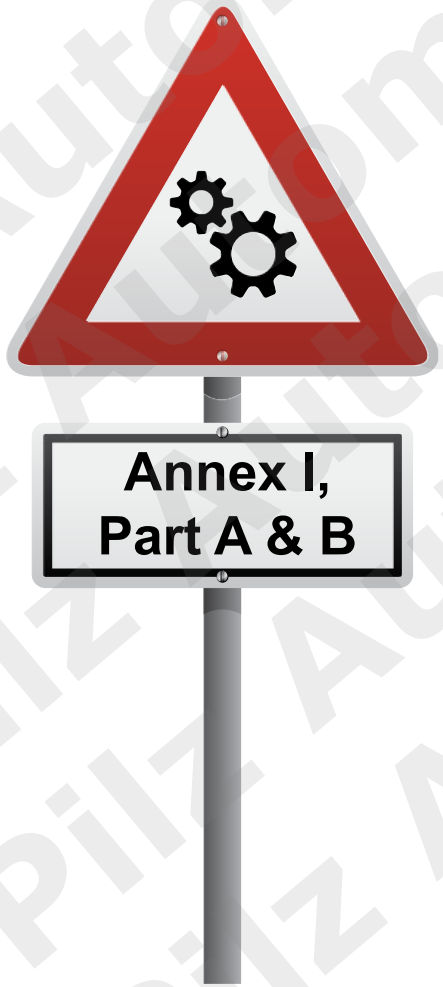
Assess your machine modifications



Organisational changes

New addition to MR

Machines subject to mandatory type-examination / involvement of NB



- Annex I (former Annex IV), contains an exhaustive list of machinery that, in general, are considered to be more hazardous than other types of machinery
- **Annex I – Part A**
  - The regulation has been intensified as such that even with application of harmonised standards it does **NOT** exempt from the obligation to use a notified body (NB)
  - Six machine types/categories are subject to inspection, for example
    - Vehicle servicing lifts
    - Machinery that has embedded systems or safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions.
- **Annex I – Part B**
  - The regulation has **not changed considerably** in part B for those remaining machine types from the former Annex IV from MD.
  - These machineries need to be type-examined (or other modules involving a notified body) only if not designed and constructed in full accordance with harmonised standards

Note: In the future, the list of machinery in the Annex I will receive frequent updates

Get support with conformity assessment

Organisational changes

Conformity Assessment Procedure

New addition to MR

- Conformity assessment is the process, carried out by the manufacturer demonstrating if specified requirements relating to a product are fulfilled
- Conformity Assessment Procedure is also known as CAP
- Machinery is subjected to conformity assessment both during design & production phase
- There are 8 possible conformity modules (methods) defined in the NLF
- Some of the modules require the use of Notified Bodies
- Machinery Regulation is using 5 of those methods

Get support with conformity assessment

Organisational changes

New addition to MR

Conformity assessment procedures based on modules of the New Legislation Framework (NLF)

DESIGN PRODUCTION

Module A

Design

+

Internal control of production

Module B

Type examination

Notified body:
- ascertains conformity of a type

Module C

Internal Control of production (Conformity to type)

Module D

QS production process

Notified body – certifies QS system

Module E

QS production line

Notified body – certifies QS system

Module F

Product samples

Notified body – verifies conformity of products

Module G

Unit verification

Notified body – verifies conformity of each unit

Module H

Full quality assurance

Notified body – certifies QS system

Notified Body involvement

Manufacturer only

Not defined in machinery regulation

New

- **Module A** is only possible for Machines which are not in Annex I, or which are part of Annex I – Part B and when harmonised Standard(s) are fully applied

Get support with conformity assessment

1.3

- Technical changes (Essential Safety Requirements)

Technical changes

What's new in Machinery Regulation

New addition to MR

Industrial Security becomes an essential part of the Machinery Regulation

While the term is not explicitly mentioned, it defines:

- Protection against corruption:
  - Legitimate or illegitimate intervention in the software
  - Modification of the software installed
- Reliability of control systems
  - Malicious attempts from third parties
  - Accidental or intentional corruption

Note: Further guidance through harmonised standards is required.

Secure your machinery control systems

Technical changes

Introducing: important new features of the Machinery Regulation

- Protection against corruption:

  Machinery shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery product or its configuration […]; This evidence to be stored at least for one year

NEW

- Requirements for safety and reliability of control systems:

  Can withstand [...] malicious attempts from third parties […] shall not lead to hazardous situations […] shall be […] protected against accidental or intentional corruption […];

As such, Industrial Security becomes an essential part of the Machinery Regulation.

However, further details through harmonised standards are required.

Technical changes

What’s new in Machinery Regulation

Safety and Industrial Security – different "protection" functions

Safety

Protects people from hazards due to machinery

Technical changes

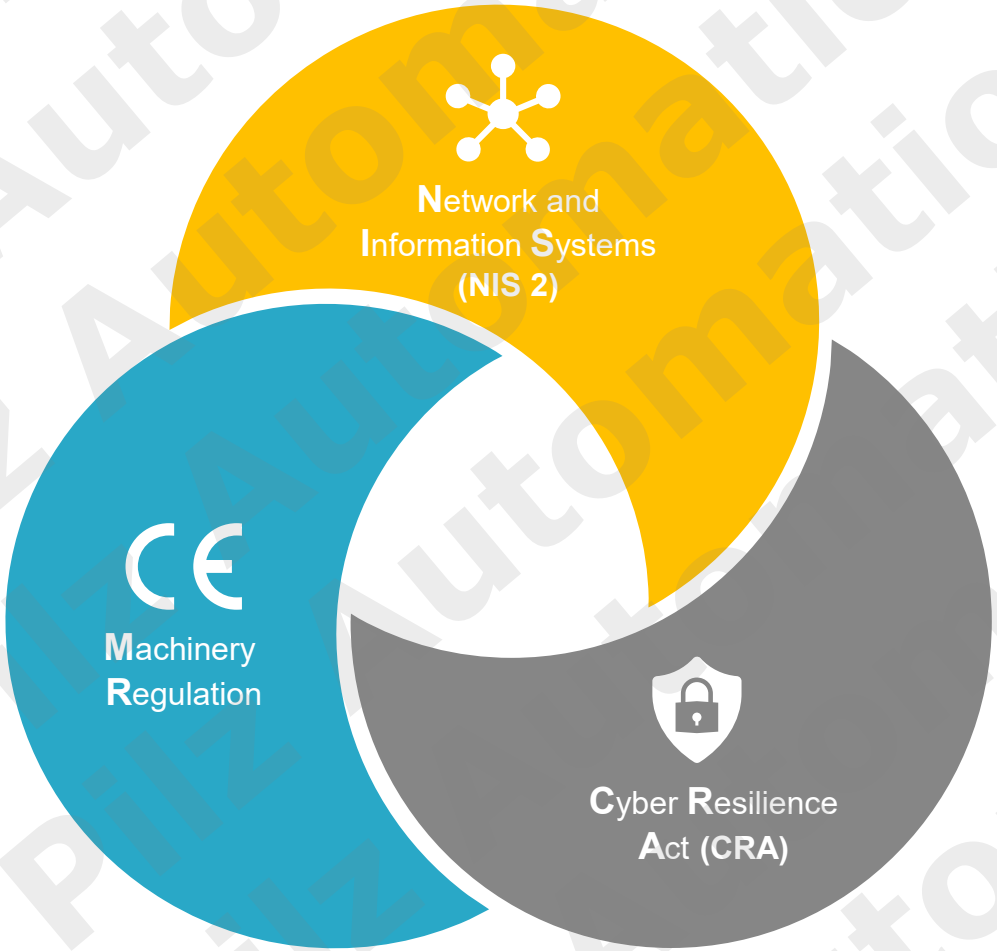
Safety and Industrial Security – different "protection" functions

Security

Protects machine and data from manipulation and unauthorised access

Technical changes

Machinery Safety and Industrial Security in transformation



Network and Information Systems (NIS 2)

(Published in the Official Journal of the European Union on 27th December 2022)

Addresses essential and important entities:

- Measures to manage cybersecurity risks
- Compliance with technical and organizational measures
- Incident reporting obligations

Machinery Regulation

(Publication June 2023 - Validity starts on 20.1.2027)

- Requirements for machinery:
- Protection against corruption (with focus on machinery safety functions)

Cyber Resilience Act (CRA)

(First draft from September 2022)

Manufacturer's obligation for products with digital elements:

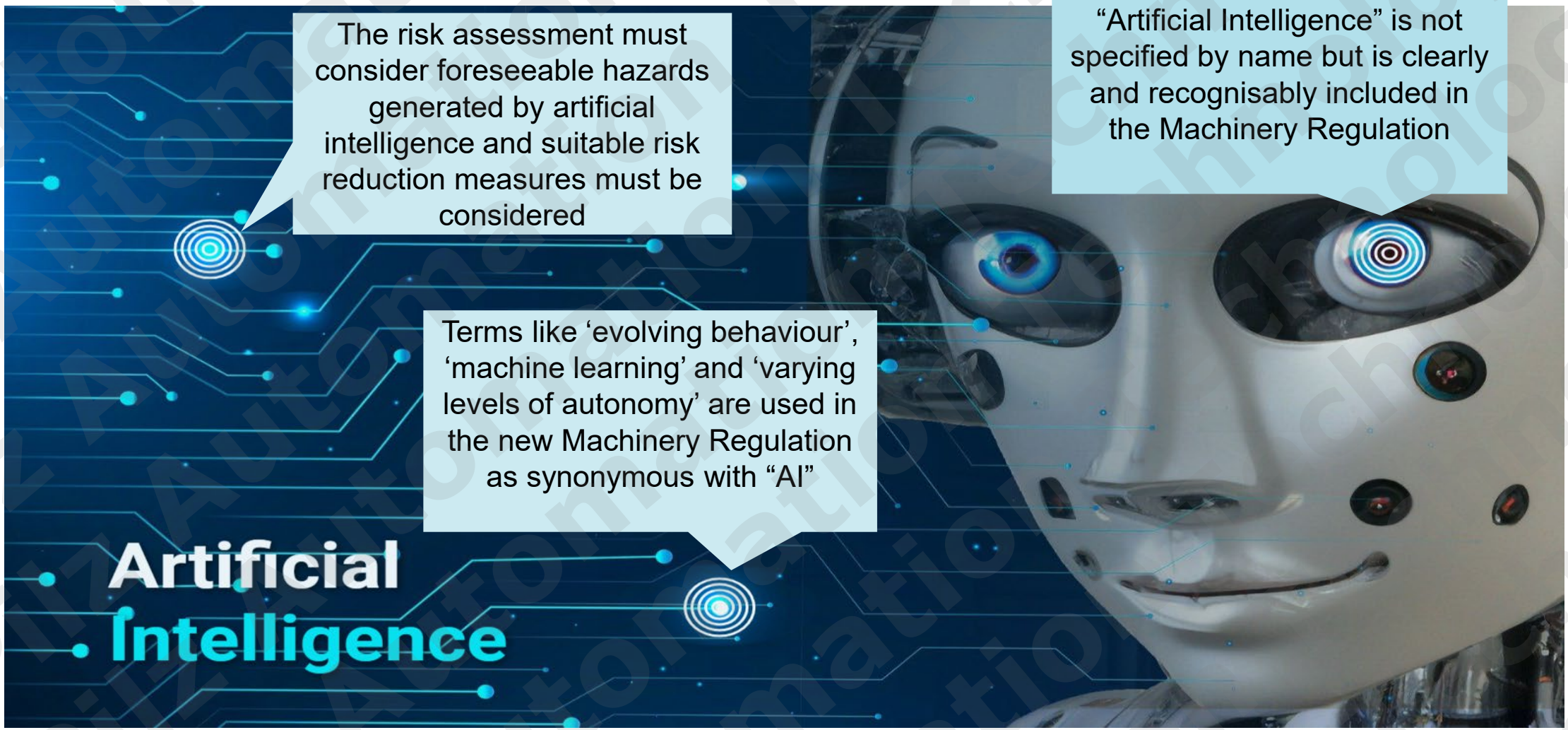
- Secure Development Lifecycle Process
- EU-Type examinations for critical products
- Report vulnerabilities
- Security updates

Secure your machinery control systems

Technical changes

What's new in Machinery Regulation

New addition to MR



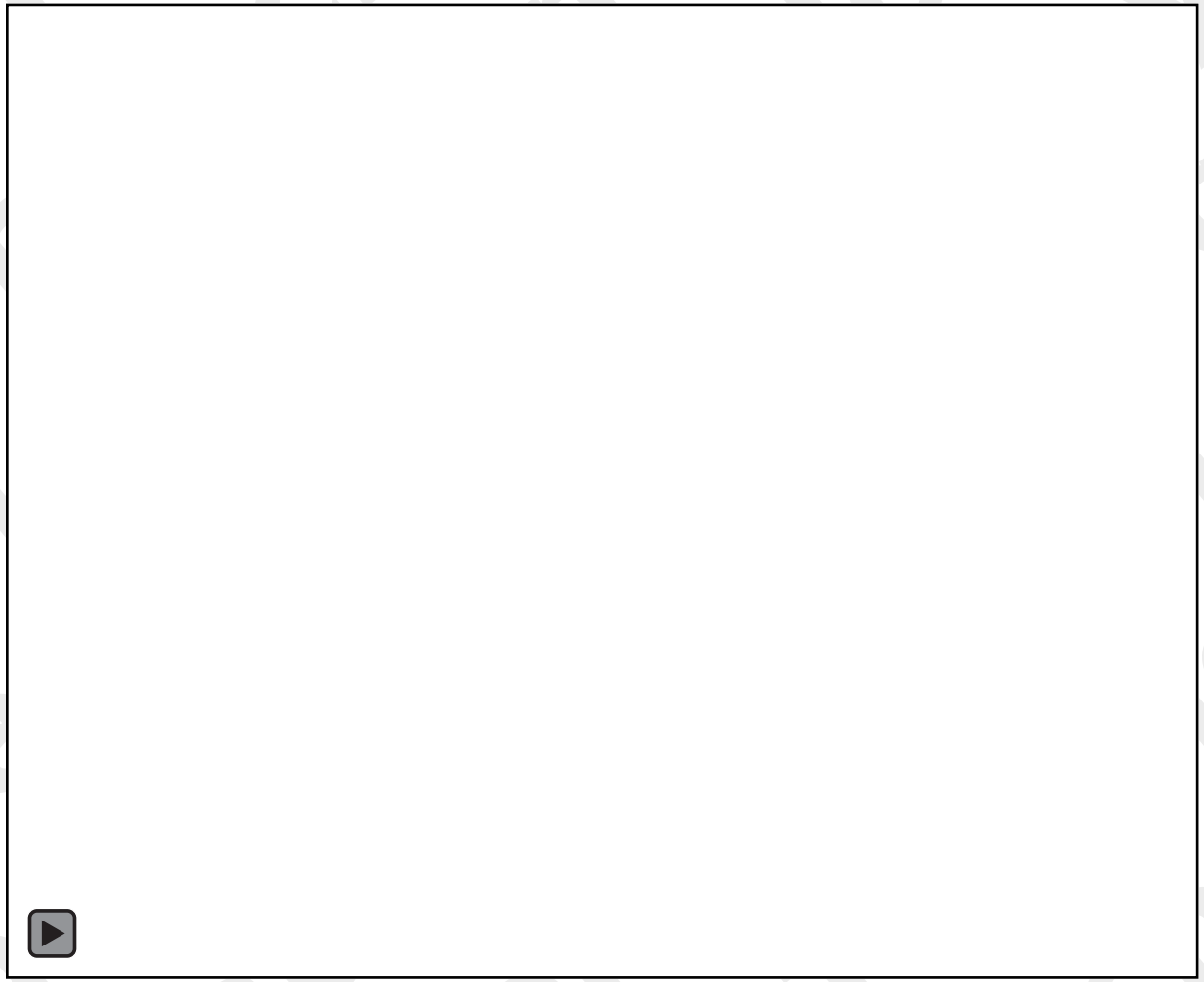
Technical changes

What’s new in Machinery Regulation

New addition to MR

Autonomous Mobile Machinery

- Autonomous mobile machinery is now specifically mentioned in Annex III
- In order to enable remote control tasks of those machines, a supervisory function specific to the autonomous mode was defined
- This function is intended to ensure that the Autonomous mobile machinery can be stopped and started safely remotely
- Without this function, the machine may not be operated
- Safety functions need to perform independently of the supervisory function
- Another interesting addition is that the area where autonomous mobile machinery is intended to work needs to be risk assessed



Essential Safety Requirements

Machinery Regulation

New addition to MR

- As part of the CE Marking process, machinery must fulfil the essential health and safety requirements (ESR) laid out in Annex III
- The ESR's are divided into two parts, Part A and Part B.
- **Part A** section defines people and objects around the machine, such as the exposed person, danger zone and operator
- **Part B** of Annex III is divided into six parts and mainly focused on general principles …

Start your machinery risk assessment here

Essential Safety Requirements

Machinery Regulation ESR's – Section 1

New Updates in MR

	Part A	**Definitions**
	Part B	**General Principles**
1.1	General remarks	
	1.1.1	Applicability
	1.1.2	Principles of safety integration
	1.1.3	Materials and products used
	1.1.4	Integral lighting
	1.1.5	Handling of machinery and parts of machinery
	1.1.6	Ergonomic principles
	1.1.7	Operating positions in hazardous environments
	1.1.8	Seating and the provision of seats
	1.1.9	Protection again corruption
1.2	Control Systems	
	1.2.1	Safety and reliability of control systems
	1.2.2	Control devices
	1.2.3	Control of starting
	1.2.4	Stopping
	1.2.4.1	Normal stop control devices
	1.2.4.2	Operational stop
	1.2.4.3	Emergency stop devices
	1.2.4.4	Stop controls for assemblies of machinery
	1.2.5	Mode selection
	1.2.6	Failure of the power supply or Network communication

1.3	Protection against mechanical hazards	
	1.3.1	Stability
	1.3.2	Break-up during operation
	1.3.3	Falling or ejected objects
	1.3.4	Sharp edges and angles and rough surfaces
	1.3.5	Combined machinery
	1.3.6	Variations in operating conditions
	1.3.7	Moving parts
	1.3.8	Choice of protection against risks arising from moving parts
	1.3.8.1	Moving transmission parts
	1.3.8.2	Moving parts involved in the process
	1.3.9	Uncontrolled movements
1.4	Required characteristics of guards and protective devices	
	1.4.1	General requirements for guards and protective devices
	1.4.2	Special requirements for guards
	1.4.2.1	Fixed guards
	1.4.2.2	Interlocking movable guards
	1.4.2.3	Adjustable guards restricting access
	1.4.3	Protective devices

1.5	Risks due to other hazards	
	1.5.1	Electricity
	1.5.2	Unwanted static electricity
	1.5.3	Energy supply other than electricity
	1.5.4	Errors of fitting
	1.5.5	Extreme temperatures
	1.5.6	Fire
	1.5.7	Explosion
	1.5.8	Reduction of noise emission
	1.5.9	Vibrations
	1.5.10	Ionising and non-ionising radiation
	1.5.11	External radiation
	1.5.12	Laser radiation
	1.5.13	Emissions of hazardous materials and substances
	1.5.14	Risk of being trapped
	1.5.15	Slips, trips and falls
	1.5.16	Lightning
1.6	Maintenance	
	1.6.1	Maintenance
	1.6.2	Access to operating positions and servicing points
	1.6.3	Isolation of energy sources
	1.6.4	Operator intervention
	1.6.5	Cleaning of internal parts
1.7	Information	
	1.7.1	Information and warnings on the machinery
	1.7.1.1	Information and information devices
	1.7.1.2	Warning devices
	1.7.2	Warning of residual risks
	1.7.3	Marking of machinery
	1.7.4	Instructions for use
	1.7.5	Sales literature

Essential Safety Requirements

Machinery Regulation ESR's – Section 1

New addition to MR

1.1	General remarks	
	1.1.1	Applicability
	1.1.2	Principles of safety integration
	1.1.3	Materials and products used
	1.1.4	Integral lighting
	1.1.5	Handling of machinery and parts of machinery
	1.1.6	Ergonomic principles
	1.1.7	Operating positions in hazardous environments
	1.1.8	Seating and the provision of seats
	1.1.9	Protection again corruption

1.1.2 Principles of safety integration:

- This provides the basic approach to follow to ensure assessments of all risks to health and safety for any machine during all stages of its use from design and assembly to final decommissioning and disposal
- It should take account both intended use and foreseeable misuse and "state of the art"
- Design and construction of machinery or associated items make it easy to test safety functions, including specialised tools and accessories

Start your machinery risk assessment here

Essential Safety Requirements

Machinery Regulation ESR's – Section 1

New addition to MR

1.1	General remarks	
	1.1.1	Applicability
	1.1.2	Principles of safety integration
	1.1.3	Materials and products used
	1.1.4	Integral lighting
	1.1.5	Handling of machinery and parts of machinery
	1.1.6	Ergonomic principles
	1.1.7	Operating positions in hazardous environments
	1.1.8	Seating and the provision of seats
	1.1.9	Protection again corruption

1.1.6 Ergonomic principles:

- Ergonomic design in machinery operation, which accommodates the operator's physical attributes, ensures sufficient space for body movement, minimizes the need for prolonged concentration, and adapts the interface between the operator and the machine.
- Avoiding unnecessary work postures, movements and excessive manual force exertions;
- Where applicable, adapting machinery with intended fully or partially self-evolving behaviour or logic;
- Communicate the planned actions to operators

Essential Safety Requirements

Machinery Regulation ESR's – Section 1

New addition to MR

1.1	General remarks	
	1.1.1	Applicability
	1.1.2	Principles of safety integration
	1.1.3	Materials and products used
	1.1.4	Integral lighting
	1.1.5	Handling of machinery and parts of machinery
	1.1.6	Ergonomic principles
	1.1.7	Operating positions in hazardous environments
	1.1.8	Seating and the provision of seats
	1.1.9	Protection again corruption

1.1.9 Protection against corruption:

- Safe device connection:
  - Machinery design ensure safe connection to the other devices
  - Remote communication should not lead to hazardous situations
- Prevention of hazards:
  - Construction of machinery prevents the creation of hazardous situations during device connections
  - Emphasises safety in the connection of remote device.
- Signal/data transmission component:
  - Design ensures adequate protection against accidental or intentional corruption
- Evidence collection:
  - Machinery must collect evidence of legitimate or illegitimate intervention in the hardware component

Essential Safety Requirements

Machinery Regulation ESR's – Section 1

New addition to MR

1.1	General remarks	
	1.1.1	Applicability
	1.1.2	Principles of safety integration
	1.1.3	Materials and products used
	1.1.4	Integral lighting
	1.1.5	Handling of machinery and parts of machinery
	1.1.6	Ergonomic principles
	1.1.7	Operating positions in hazardous environments
	1.1.8	Seating and the provision of seats
	1.1.9	Protection again corruption

1.1.9 Protection against corruption (continuation):

- Security emphasis:
  - Prioritises security and addresses both accidental and intentional corruption risks.
- Critical software data:
  - Identification of software and data critical for compliance with ESRs;
  - Safeguarding critical software and data to maintain compliance;
  - Recognition of the importance of security in preserving the integrity of crucial software and data.
- Machinery identifies installed software in it for safe operation and able to provide information at all time.
- User-friendly access of information
- Machinery monitors modifications to the installed software or its configuration

Essential Safety Requirements

Machinery Regulation ESR's – Section 1

New addition to MR

1.2	Control Systems	
	1.2.1	Safety and reliability of control systems
	1.2.2	Control devices
	1.2.3	Control of starting
	1.2.4	Stopping
	1.2.4.1	Normal stop control devices
	1.2.4.2	Operational stop
	1.2.4.3	Emergency stop devices
	1.2.4.4	Stop controls for assemblies of machinery
	1.2.5	Mode selection
	1.2.6	Failure of the power supply or communication network connection

1.2.1 Safety and reliability of control system

- Control system designed and constructed in a such a way that they can withstand
  - Appropriate to circumstances and risks
  - Intended and unintended external influences
  - Malicious attempts from third parties leading to hazardous situation
- The limits of the safety functions are to be established as a part of risk assessment
- Machinery must not start unexpectedly

Start your machinery risk assessment here

Essential Safety Requirements

Machinery Regulation ESR's – Section 1

New addition to MR

1.2 Control Systems	
1.2.1	Safety and reliability of control systems
1.2.2	Control devices
1.2.3	Control of starting
1.2.4	Stopping
1.2.4.1	Normal stop control devices
1.2.4.2	Operational stop
1.2.4.3	Emergency stop devices
1.2.4.4	Stop controls for assemblies of machinery
1.2.5	Mode selection
1.2.6	Failure of the power supply or communication network connection

1.2.1 Safety and reliability of control system

- Parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations
- Modifications to the settings of the machinery must be prevented from hazardous situations
- No moving part of the machinery or piece held by the machinery must fall or be ejected
- Automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded
- The protective devices must remain fully effective or give a stop command

Essential Safety Requirements

Machinery Regulation ESR's – Section 1

1.3	Protection against mechanical hazards	
	1.3.1	Stability
	1.3.2	Break-up during operation
	1.3.3	Falling or ejected objects
	1.3.4	Sharp edges and angles and rough surfaces
	1.3.5	Combined machinery
	1.3.6	Variations in operating conditions
	1.3.7	Moving parts
	1.3.8	Choice of protection against risks arising from moving parts
	1.3.8.1	Moving transmission parts
	1.3.8.2	Moving parts involved in the process
	1.3.9	Uncontrolled movements

New addition to MR

1.3.7 Moving parts

- Machinery must be designed to prevent contact with moving parts that could lead to accidents. Guards or protective devices must be installed if risks persist
- Steps must be taken to prevent accidental blockages of moving parts, and if blockages are likely, specific protective devices must be provided for safe unblocking, with instructions for use clearly identified
- The prevention of mechanical risk:
  - Human-machine coexistence in a shared space without direct collaboration
  - Human-machine interaction

Essential Safety Requirements

Machinery Regulation ESR's – Section 1

New addition to MR

1.6	Maintenance	
	1.6.1	Maintenance
	1.6.2	Access to operating positions and servicing points
	1.6.3	Isolation of energy sources
	1.6.4	Operator intervention
	1.6.5	Cleaning of internal parts

1.6.2 Access to operating position and servicing points

- Safe access:
  - Machinery must be designed to allow safe access to necessary areas during operation, adjustment, maintenance and cleaning
  - Ensure user safety and efficient maintenance
- Emergency access:
  - Access points must be dimensioned and adapted for rescue equipment
  - Ensures emergency rescue of individual if needed

Essential Safety Requirements

Machinery Regulation ESR's – Section 1

New addition to MR

1.7	Information	
	1.7.1	Information and warnings on the machinery
	1.7.1.1	Information and information devices
	1.7.1.2	Warning devices
	1.7.2	Warning of residual risks
	1.7.3	Marking of machinery
	1.7.4	Instructions for use
	1.7.5	Sales literature

1.7.3 Marking of machinery

All machinery must be marked visibly, legibly and indelibly with the following minimum particulars

- Manufacturer name, trade name, website, or digital contact
- Designation of the machinery or product model
- Batch number or identification, where the size and nature of machinery
- The contact details shall be in a language easily understood by users and market surveillance authorities.

1.7.4 Instructions for use

- When instructions are presented in digital format, instructions for use must be easily downloaded or printed and available online for at least ten years after it is placed on the market

Technical changes

MR: Rules for affixing the CE marking

- CE marking should be affixed visibly, legibly and indelibly to the machinery
- If not possible then, it should be affixed on packaging and to the documents accompanying the machinery
- It should be affixed before the machinery is placed on the market
- If the CE marking involved in CAP followed by the identification number of the notified body
  - Identification number must be affixed by Notified Body itself or under its instructions, by manufacturer or AR
- The CE marking, when applicable, can be accompanied by a pictogram or another symbol that indicates a specific risk or intended use.

New addition to MR

Minimum requirements

- Business name or AR
- Address, including digital address of manufacturer or AR
- Machinery designation
- Year of construction
- Series/Type designation
- Serial number
- The important marking
- NB number (if applicable)

Learn more about CE Marking

Technical changes

What's new in Machinery Regulation

New addition to MR

"Digital instructions" for documentation

…finally…

- In future, it will be possible to deliver machinery with digital instructions (only)
- Paper version to be provided on request (free of charge within first month)

- The EC Declaration of Conformity can also be provided in digital form
- Partly completed machinery can be delivered with digital assembly instructions as well as with a digital declaration of incorporation
- Keep it available for 10 years in digital format

Technical changes

Affix CE Mark - Declaration of Conformity

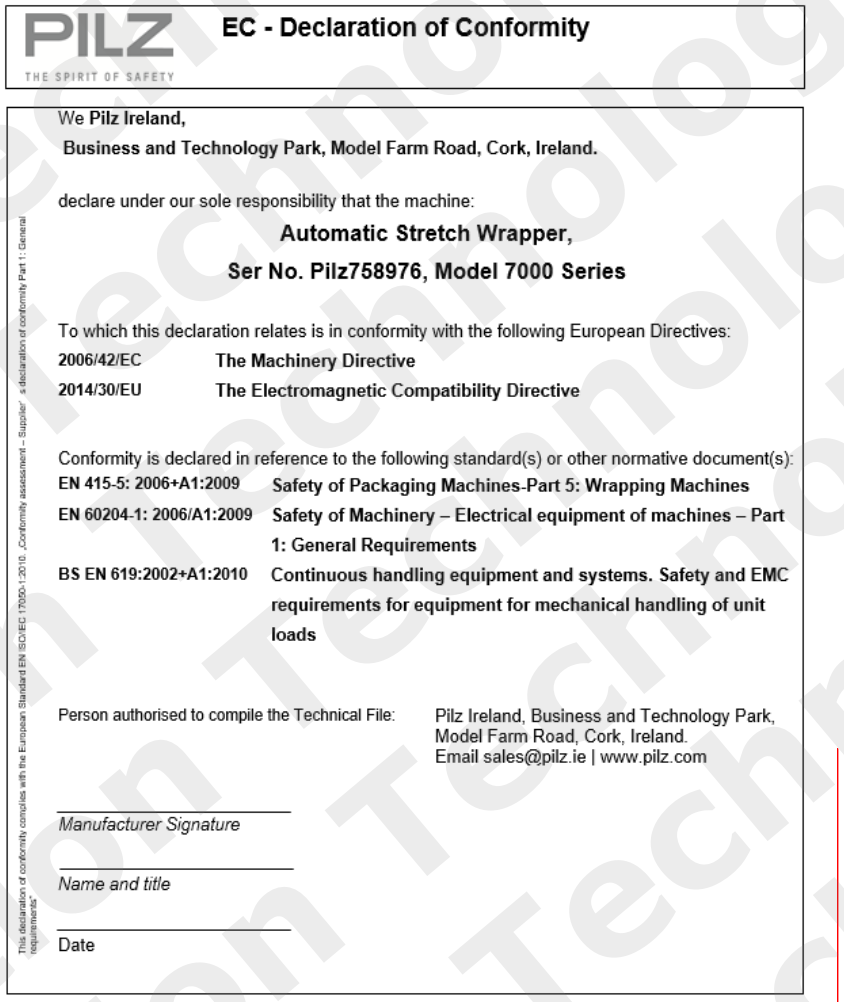
New addition to MR

Example of DoC Template:

- Manufacturer name and address
  - If mandated, the AR data and Manufacturer name
- Machine References (product, type, model, serial #)
  - If substantial modification, must be referred too
- Regulations and Directives
- Harmonised Standards
- Identifications and signature
- Where applicable, the notified body (name and number) and the CAP with certificate number.

Note 1: Based on MR, the DoC must be issued under the sole responsibility of the manufacturer

Note 2: MD requires the person authorised to compile the technical documentation shall be mentioned in the DoC, however for MR is no longer necessary.



PILZ
THE SPIRIT OF SAFETY

EC - Declaration of Conformity

We **Pilz Ireland,**
Business and Technology Park, Model Farm Road, Cork, Ireland.

declare under our sole responsibility that the machine:

Automatic Stretch Wrapper,
Ser No. Pilz758976, Model 7000 Series

To which this declaration relates is in conformity with the following European Directives:

2006/42/EC	The Machinery Directive
2014/30/EU	The Electromagnetic Compatibility Directive

Conformity is declared in reference to the following standard(s) or other normative document(s):

EN 415-5: 2006+A1:2009	Safety of Packaging Machines-Part 5: Wrapping Machines
EN 60204-1: 2006/A1:2009	Safety of Machinery – Electrical equipment of machines – Part 1: General Requirements
BS EN 619:2002+A1:2010	Continuous handling equipment and systems. Safety and EMC requirements for equipment for mechanical handling of unit loads

Person authorised to compile the Technical File: Pilz Ireland, Business and Technology Park, Model Farm Road, Cork, Ireland. Email sales@pilz.ie | www.pilz.com

Manufacturer Signature

Name and title

Date

This declaration of conformity complies with the European Standard EN ISO/IEC 17050-1:2010. Conformity assessment – Supplier's declaration of conformity Part 1: General requirements

Learn more about CE Marking

Affix CE Mark and Declaration

Example – Declaration of Incorporation

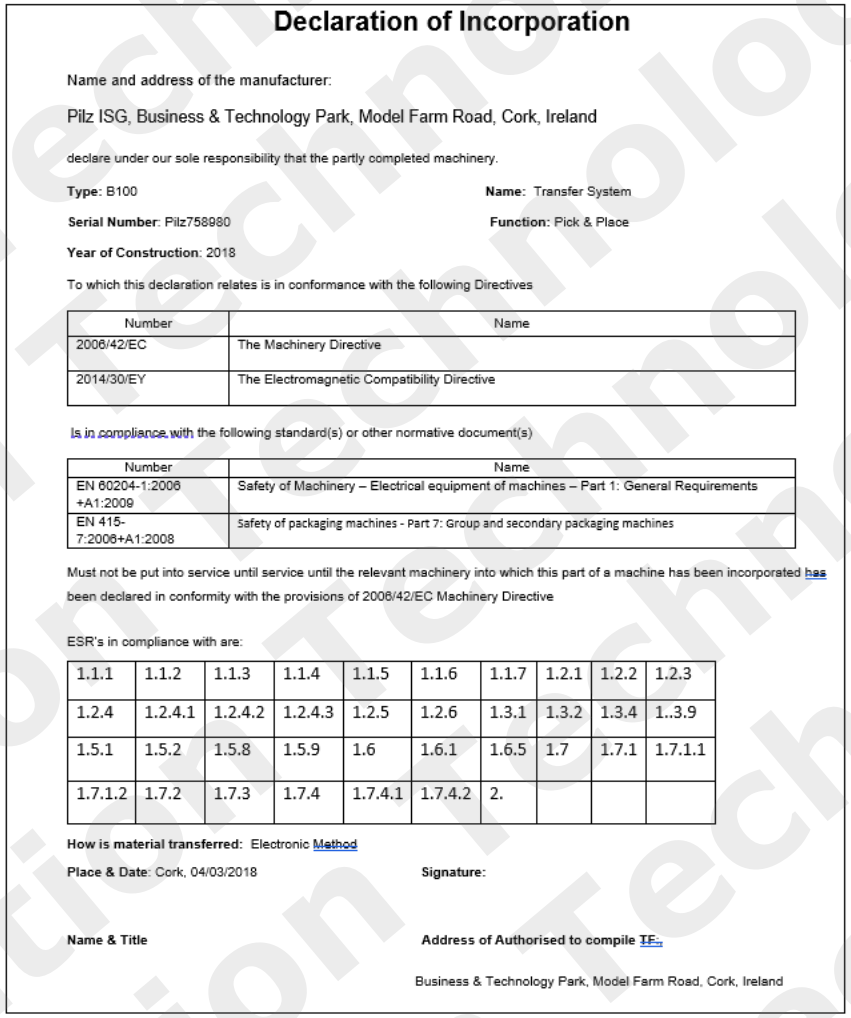
New addition to MR

Partly completed machinery, should be issue a Declaration of Incorporation (DoI) instead of a DoC

Key elements of a DoI:

- Same elements of DoC
- Additionally, the DoI must state the fulfilment of the relevant essential safety requirements

Note: Where partly completed Machinery is subject to more than one legislation requiring a DoC, the DoI shall include a sentence declaring the conformity with such legislation.



Declaration of Incorporation

Name and address of the manufacturer:

Pilz ISG, Business & Technology Park, Model Farm Road, Cork, Ireland

declare under our sole responsibility that the partly completed machinery.

Type: B100 **Name:** Transfer System

Serial Number: Pilz758980 **Function:** Pick & Place

Year of Construction: 2018

To which this declaration relates is in conformance with the following Directives

Number	Name
2006/42/EC	The Machinery Directive
2014/30/EY	The Electromagnetic Compatibility Directive

Is in compliance with the following standard(s) or other normative document(s)

Number	Name
EN 60204-1:2006 +A1:2009	Safety of Machinery – Electrical equipment of machines – Part 1: General Requirements
EN 415-7:2006+A1:2008	Safety of packaging machines - Part 7: Group and secondary packaging machines

Must not be put into service until service until the relevant machinery into which this part of a machine has been incorporated has been declared in conformity with the provisions of 2006/42/EC Machinery Directive

ESR's in compliance with are:

1.1.1	1.1.2	1.1.3	1.1.4	1.1.5	1.1.6	1.1.7	1.2.1	1.2.2	1.2.3
1.2.4	1.2.4.1	1.2.4.2	1.2.4.3	1.2.5	1.2.6	1.3.1	1.3.2	1.3.4	1..3.9
1.5.1	1.5.2	1.5.8	1.5.9	1.6	1.6.1	1.6.5	1.7	1.7.1	1.7.1.1
1.7.1.2	1.7.2	1.7.3	1.7.4	1.7.4.1	1.7.4.2	2.			

How is material transferred: Electronic Method

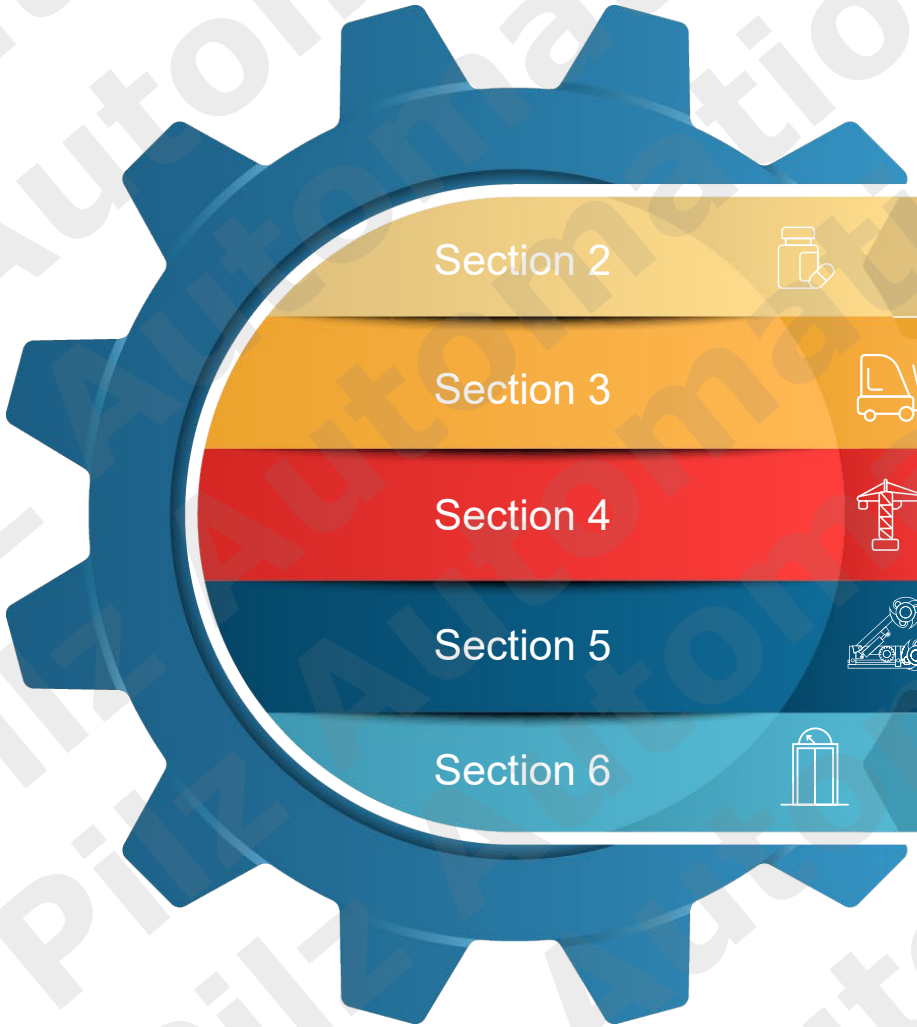
Place & Date: Cork, 04/03/2018 **Signature:**

Name & Title **Address of Authorised to compile TF.**

Business & Technology Park, Model Farm Road, Cork, Ireland

Essential Safety Requirements

Machinery Regulation - Supplementary Requirements for particular types of machinery



Section 2	Foodstuffs, Cosmetics, Pharmaceutical, Hand-held, Wood, Agricultural,..
Section 3	Requirements to offset hazards arising from the mobility of equipment
Section 4	Requirements to offset hazards arising from lifting operations
Section 5	Requirements for machinery intended for use underground
Section 6	Concerned with machinery designed to lift and move people

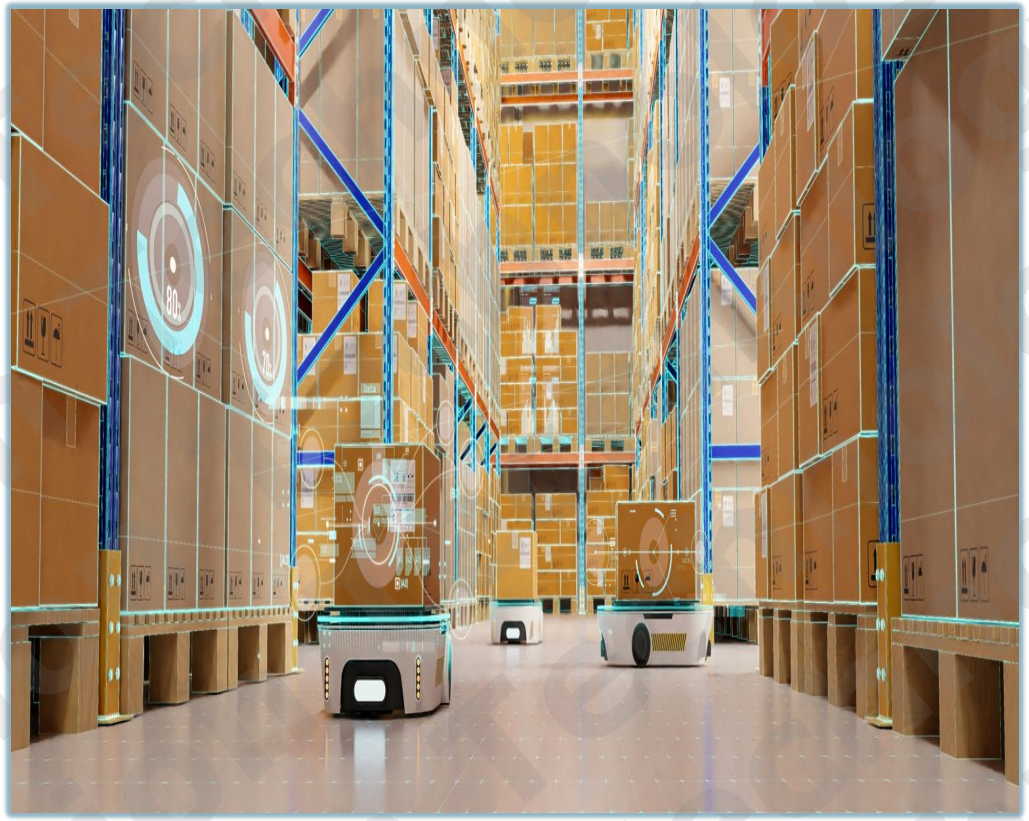
Essential Requirements

New addition to MR

Machinery Regulation

Section 3. Supplementary ESR to offset risks due to the mobility of machinery or related products

- Machinery, including autonomous mobile machinery (e.g., AGV), which presents risks due to their mobility shall meet supplementary essential health and safety requirements
- This equipment can be guided by a driver (transported by the machinery, or accompanying the machinery on foot, or using a remote control)
- Special aspects must take in account:
  - Work position
  - Supervisory safety functions of autonomous mobile machinery
  - Travel and Start/Stop functions
  - Mechanical risk, e.g., uncontrolled movement, moving transmission parts, etc.
  - Batteries and related risk (fires, dangerous substances, etc.)
  - Protective systems or devices in relation to travelling function
  - Failure in the steering system shall not have an impact on safety

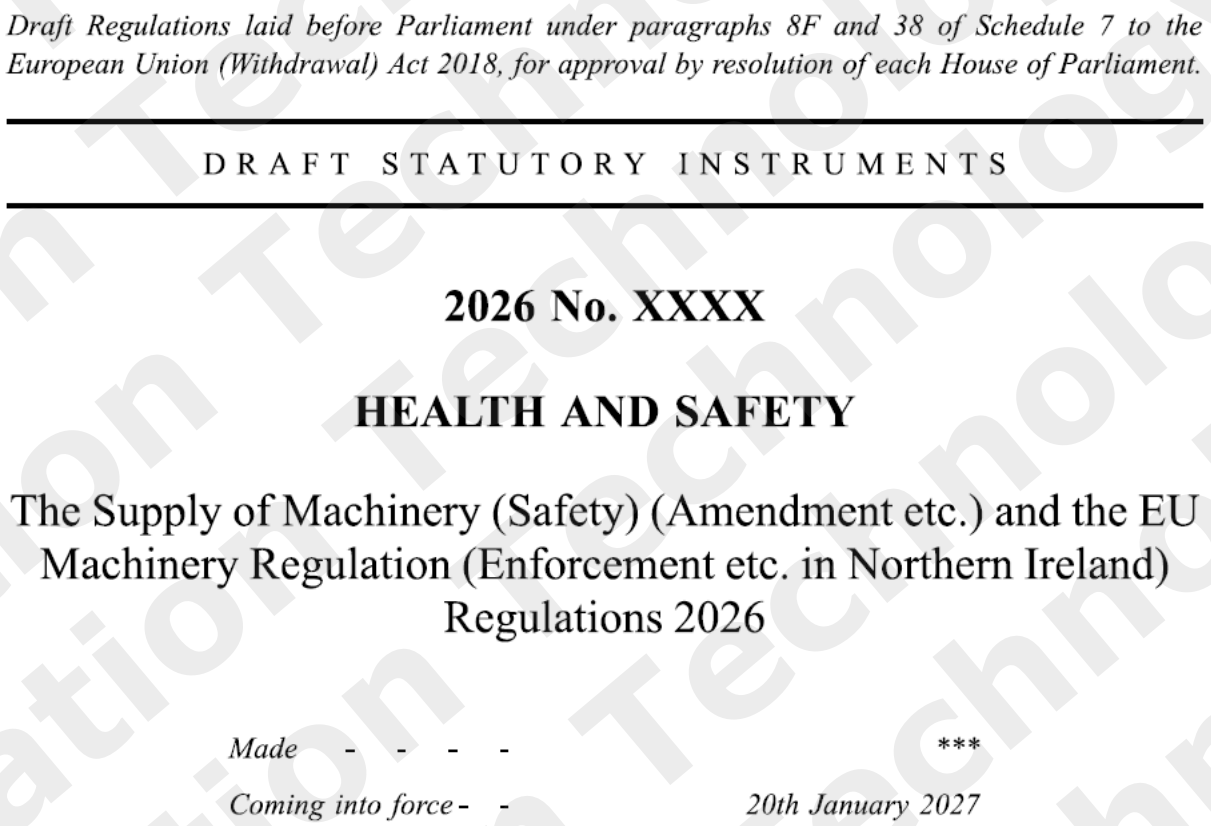


1.4

- What does this mean for the UK

UK Supply of Machinery (Safety) Regulation - Update

- **1 June 2026:** The UK government officially laid the draft Statutory Instrument—the *Supply of Machinery (Safety) (Amendment etc.) and the EU Machinery Regulation (Enforcement etc. in Northern Ireland) Regulations 2026*—before Parliament for approval
- **20 January 2027:** This is the exact date the regulations officially **come into force** across England, Scotland, Wales, and Northern Ireland. It perfectly aligns with the EU enforcement date for EU Machinery Regulation
- **There is no transition or grace period after January 2027**



Draft Regulations laid before Parliament under paragraphs 8F and 38 of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2026 No. XXXX

HEALTH AND SAFETY

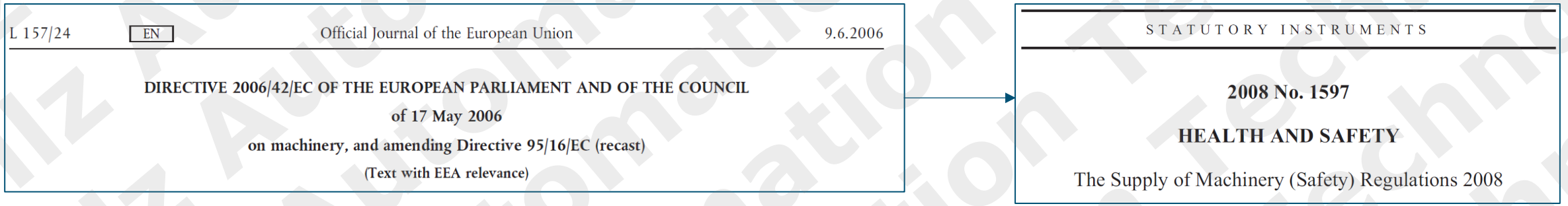
The Supply of Machinery (Safety) (Amendment etc.) and the EU Machinery Regulation (Enforcement etc. in Northern Ireland) Regulations 2026

Made - - - - ***

Coming into force - - *20th January 2027*

Current EU & UK Legislation

- New Approach Directives stipulating Essential Requirements are transposed into national legislation.
- In the UK, this has been achieved through Statutory Instruments for many years, and published as Regulations.
- For example, EU Machinery directive 2006/42/EC was transposed into the 2008 Supply of Machinery (Safety) Regulations by the Statutory Instrument SI 1597/2008.



L 157/24 EN Official Journal of the European Union 9.6.2006

DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 17 May 2006
on machinery, and amending Directive 95/16/EC (recast)
(Text with EEA relevance)

STATUTORY INSTRUMENTS

2008 No. 1597

HEALTH AND SAFETY

The Supply of Machinery (Safety) Regulations 2008

Talking Points Regarding the Current Status of The Transition to the New Machinery Regulation

- No Current Harmonised Standards
- HAS Consultants reviewing all the current standards – Approx 700

Talking Points on the Pathway to Transition to the New Machinery Regulation

- Machinery Supplied before January 20th 2027 but included within an assembly of machine after this date
- Gap Analysis between the New Machinery Regulation and Machinery Directive
- Cyber Resilience Act and NIS 2 not being adopted by UK Government

Compliance and conformity
All machinery placed on the EU market before 20 January 2027 must comply with the current Machinery Directive 2006/42/EC. Manufacturers are allowed to state on an EU Declaration of Conformity that such machinery also conforms with Machinery Regulation (EU) 2023/1230 if applicable.

Learn more about the Machinery Regulation

Training Portfolio
Qualification Paths

Introduction	# days
Introduction to Machinery Safety	1
Safety Technology	web
Machinery Safety	web

Fundamental	# days
Fundamentals of Machinery Safety	2
Management of Risk in Machinery Procurement	1
Risk Assessment Workshop	1
LOTO Lock Out Tag Out	1
Robot Safety	1
PNOZmulti - Programming and Service	1
Visualisation with PASvisu - Programming	1
Service Robotic Modules – Programming and Service	1

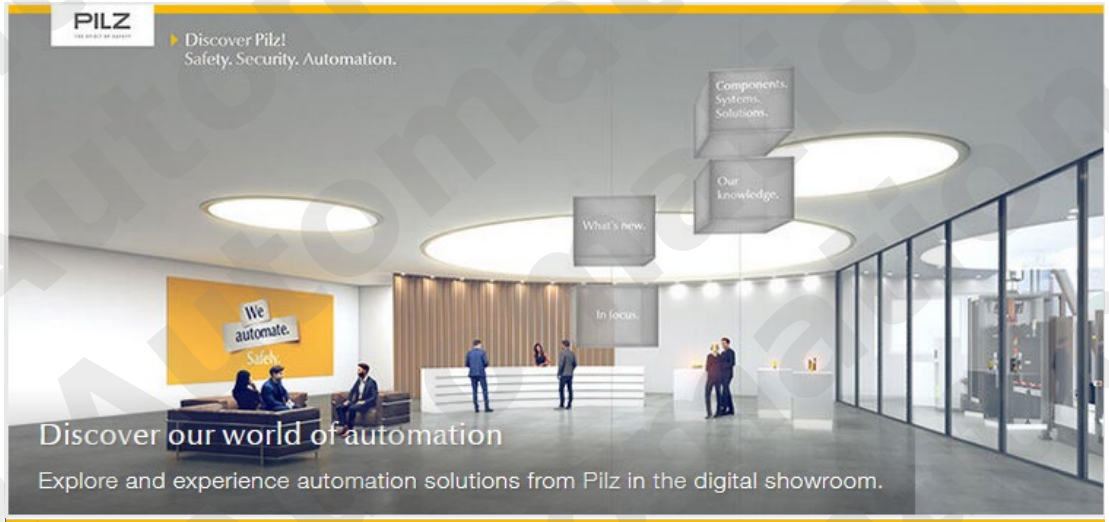
Advanced	# days
Safety Design inc. ISO13849 & IEC 62061	1
Electrical Safety in Industrial Installations	1
Safe human-robot collaboration	1
Workshop HRC collision measurement set	1
Automation system PSS 4000 with control system PSSuniversal PLC	1
Basis of CE Marking	1
City & Guilds – Key Aspects of Machine Safety	4

Expert	# days
Certified Machinery Safety Expert (CMSE)	4
CMSE Recertification	1
Certified Expert in CE Marking (CECE)	2
Certified Expert in Functional Safety(CEFS)	2

Progress through the stages to Expert Level

Machinery Safety & Security courses

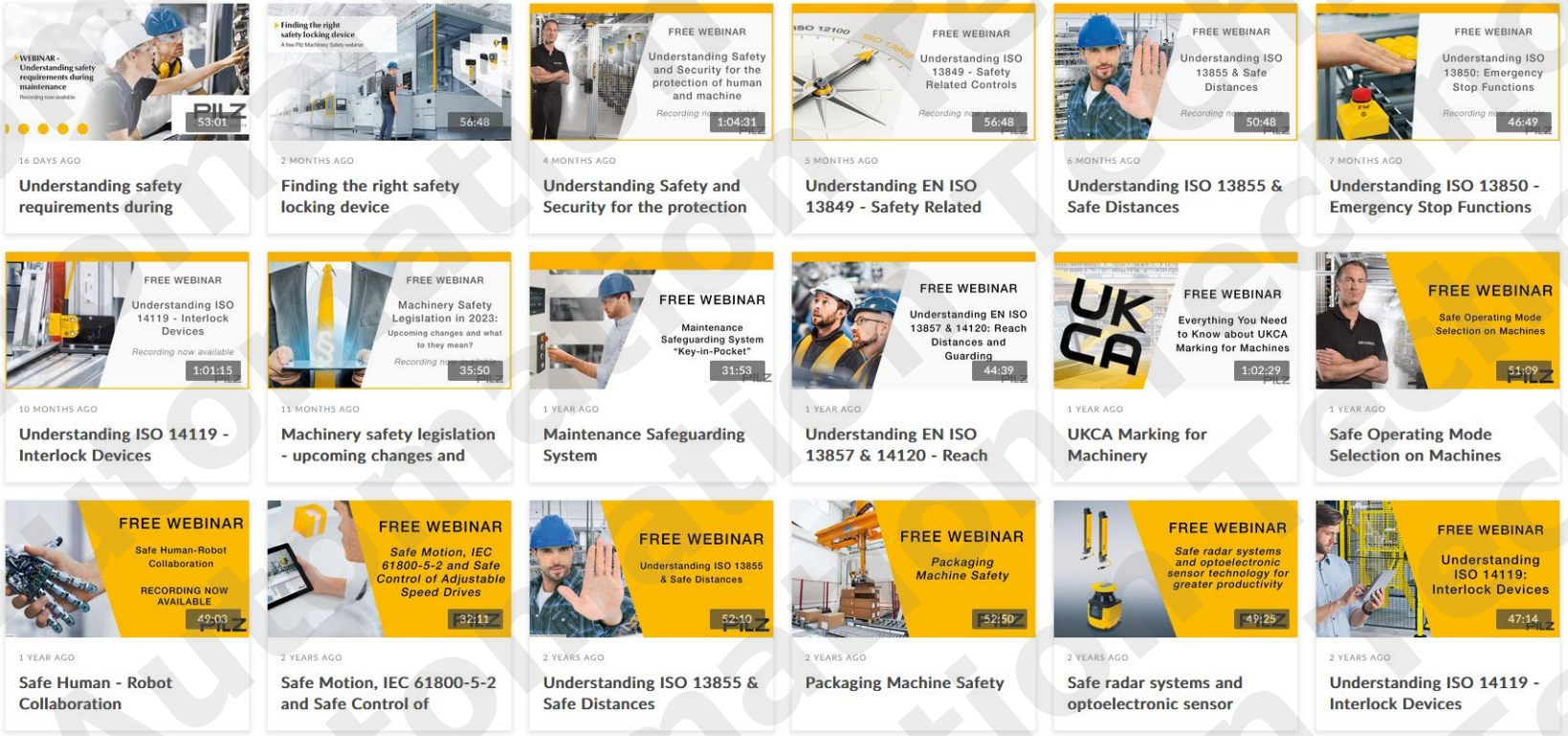
Stay up to date with the Pilz website



See product information in the Pilz Digital Showroom

See application solutions on a virtual machine, keep up to date with safety announcements, check what new products have been launched all in our digital showroom that easily accessed via the Pilz website

Stay up to date with the Pilz webinar channel



Catch Up on Previous Machinery Safety Webinars

Pilz UK has a dedicated webinar channel which plays host to a collection of previously broadcast Machinery Safety presentations

This gives you the opportunity to brush up on your machinery safety knowledge in your own time or revisit previously watched webinars to be reminded of key standards and technologies.

Thanks for attending this Pilz Machinery Safety Webinar

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THE SPIRIT OF SAFETY