

# Navigating the New EU Machinery Safety Requirements: What's on the Horizon?



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Q&A Session

Slides & Webinar  
Recording



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Ensure global companies have the tools & information to build safe, sustainable, products in a world full change

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**logitech**

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**Thermo**  
SCIENTIFIC

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87k+  
Regulations

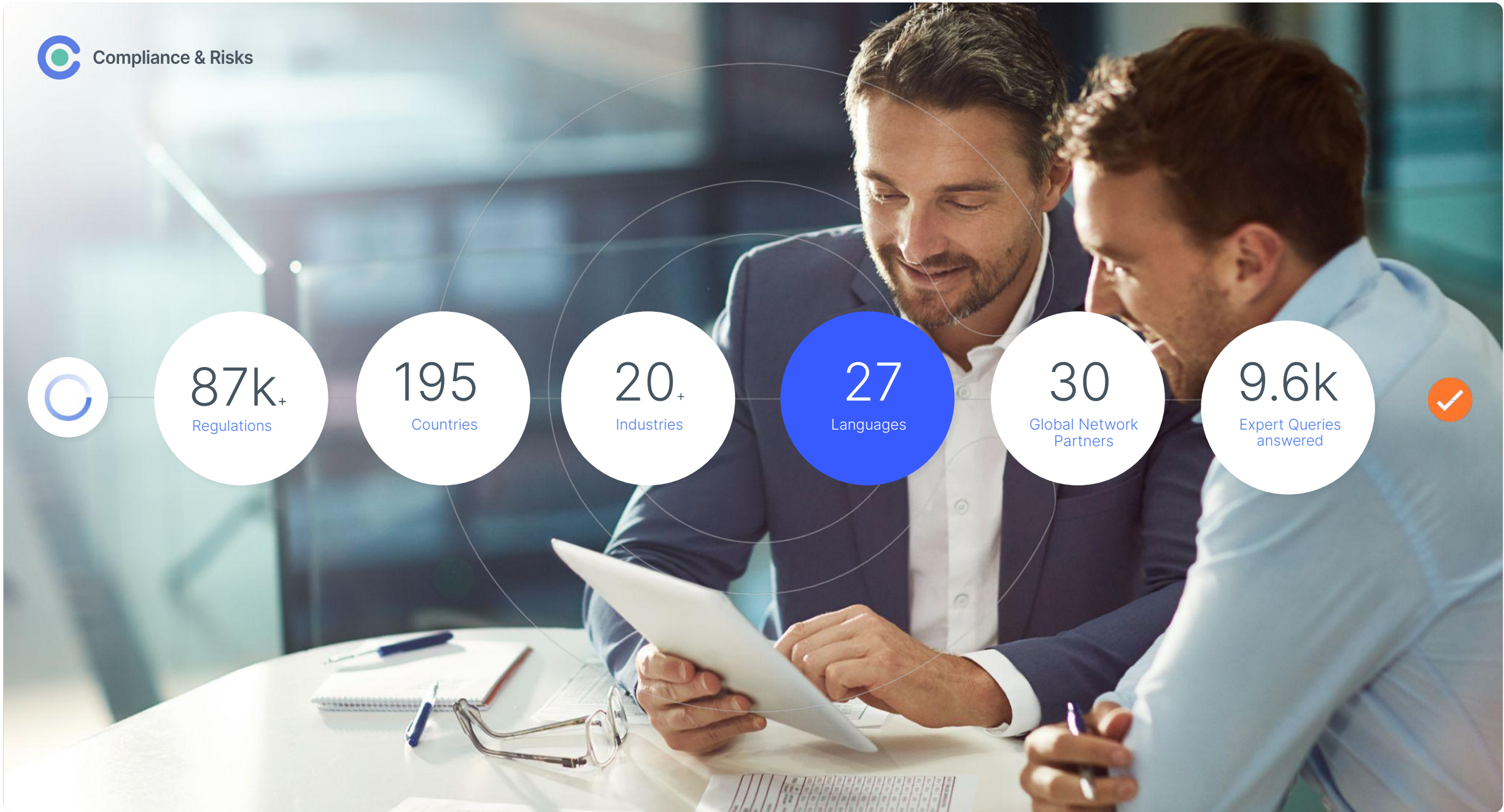
195  
Countries

20+  
Industries

27  
Languages

30  
Global Network  
Partners

9.6k  
Expert Queries  
answered



WHAT WE DO

# Unlocking Market Access

Keep on top of regulatory changes and their impact worldwide. Early warning alerts, impact probability, productivity workflow tools and so much more.



02

# RINA Overview



# RINA Tech UK Ltd

## – Regulatory Compliance Group

We support authorities, manufacturers, importers and distributors of products, to identify, understand and meet technical and environmental legislation.



Global Market Access

- Low Voltage
- Electromagnetic Compatibility (EMC)
- Pressure equipment
- Radio Equipment
- Medical Devices
- Machinery
- Hazardous Area (ATEX)
- Substances (RoHS/REACH/CLP/BPR/POPs/Cal. Prop. 65)
- Ecodesign
- Electrical waste (WEEE)
- Batteries
- Conflict Minerals
- Transportation

02

# New EU Machinery Safety Legislation

# Webinar Objectives

To outline the new regulatory requirements applying to the placing on the EU market and putting into service of machinery products.

- Summary of the current regulatory requirements are.
- Background - Why the EU has acted to develop and expand these requirements.
- What the new requirements are, and the potential implications for economic operators.
- Relevant timings.
- Next steps.

# EU Machinery Products Legislation

The Machinery Directive 2006/42/EC



# Machinery Directive 2006/42/EC

Remains in force until 2027.

## Aim:

- Enables machinery that meets the health and safety requirements to be moved freely throughout the EU.
- Protects workers and the public when they use or come into contact with machinery.

## Scope:

- The Directive covers machinery, interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing, removable mechanical transmission devices and partly completed machinery.
- Excluded from scope are, machinery used in fairgrounds, the nuclear industry, laboratories and mines or by the military or police.



# Machinery Directive 2006/42/EC

## Conformity Assessment:

- Applies at the point the machinery is put into service or placed on the market.
- Self-assessment – Applies to the majority of products.
- Annex IV list (23) – If harmonised standards have been applied and they cover all the EHSRs then there's a choice of:
  - Self assessment
  - EC type-examination + internal checks
  - Or full quality assurance procedure.

If harmonised standard haven't been used then the last two bullet points only.



# Machinery Directive 2006/42/EC

## Manufacturer's Obligations

Manufacturers must:

- Perform Risk Assessment.
- Identify which **health and safety requirements** apply to their machinery.
- Design and build machinery making sure it complies with the applicable EHSRs, listed in Annex 1 of the Directive.
- Draw up a technical file confirming that the machinery meets the Directive's requirements.
- Provide all necessary information, including instructions for safe assembly and use.
- Draw up an EC **Declaration of Conformity** and ensure that the CE conformity marking has been put on the machinery so that it can be used anywhere in the EU.

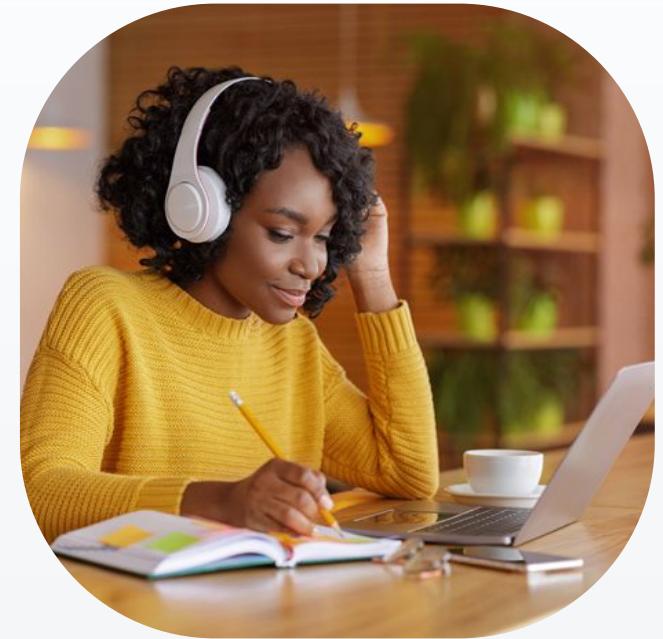


# Machinery Directive 2006/42/EC

## Where to find more information

- Machinery Directive Guide.
- Recommendations for use (RfU) sheets.
- Harmonised Standards listing
- Application guide: ergonomic health and safety requirements (EHSR 1.1.6)
- Consolidated text of the Directive

[Link to the European Commission Website](#)





# EU Machinery Products Legislation

The Machinery Regulation 2023/1230



# Machinery Regulation 2023/1230

## Why the update ?

- Alignment
- Clarification
- To address emerging digital innovations and AI
- To address issues associated with higher risk machines



# Machinery Regulation 2023/1230

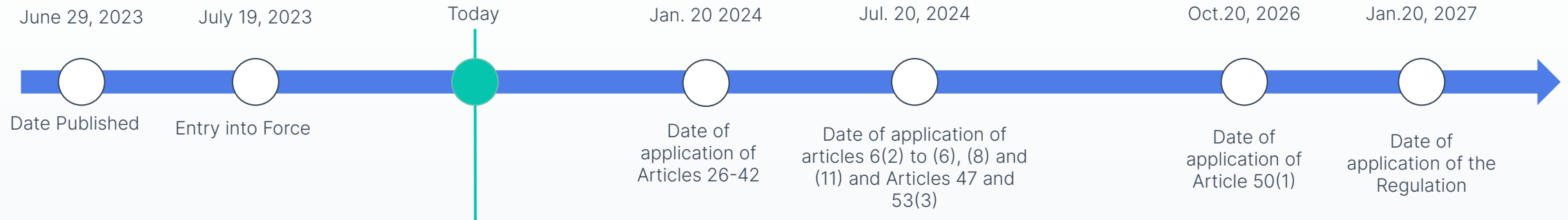
What's the difference and why the change from a Directive to a Regulation?

- Reduce administrative burden on member states and economic operators.
- Avoid different national interpretations



# Machinery Regulation 2023/1230

## Timeline



**January 20th 2024** (Art.54, a): Date of application of Articles 26-42 – Notification of Conformity Assessment Bodies

**July 19th 2023** (Art. 52,1): Chapter VI of 2023/1230 shall apply to products placed on the market in conformity with 2006/42/EC instead of article 11 in 2006/42/EC – Market Surveillance

**July 20th 2024** (Art.54,d): Date of application of Article 6 (2) to (6) and (11) and Article 47 and 53(3)  
Article 6(2) to (6) and (11) – Allows the commission to make amendments to the Annex 1 product listing.  
Article 47 and 53(3) - Authorises the commission to adopt delegated acts

**October 20th 2026** (Art.54,b): Date of application of Article 50(1) - Member states declare Penalties

**January 20th 2027** (Art. 54,2): Date of application of the Regulation and the date 2006/42/EC is repealed

**Note:** EC type examination certificates and approval decisions issued in accordance with Article 12 of 2006/42/EC shall remain valid until they expire.

# Machinery Regulation 2023/1230

## Document Structure

Changed Consequence: Internal document updates may be required.

2006/42/EC	Content	EU 2023/1230
Annex I	EHSRS	Annex III
Annex II	Declaration of Conformity	Annex V
Annex III	CE Marking	-
Annex IV	Higher Risk Machinery List	Annex I
Annex V	Safety Component List	Annex II
Annex VI	Assembly Instructions	Annex XI
Annex VII	Technical File	Annex IV
Annex VIII	Internal checks on the manufacture of machinery	Annex VI & VIII
Annex IX	EX Type- Examination	Annex VII
Annex X	Full quality insurance	Annex IX
Annex XI	Notified Body criteria	Article 30
Annex XII	Correlation Table	Annex XII

Refer to the correlation table in Annex XII.

# Machinery Regulation 2023/1230

## Scope and Exclusions

### Scope:

- Terminology change: The new regulation 2023/1230 refers to "machinery and related products"
- Legislation citations updated
- In-scope machinery & related products remain the same

### Exclusions:

- Clarification of descriptions:

(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;



(c) machinery and related products specially designed for use within or used in a nuclear installation and whose conformity with this Regulation may undermine the nuclear safety of that installation;

# Machinery Regulation 2023/1230

## Scope and Exclusions

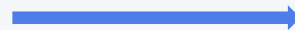
### Exclusion added:

(f) aeronautical products, parts and equipment that fall within the scope of Regulation (EU) 2018/1139 of the European Parliament and of the Council <sup>(21)</sup> and the definition of machinery under this Regulation, insofar as Regulation (EU) 2018/1139 covers the relevant essential health and safety requirements set out in this Regulation;

### Exclusions refined:

(k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits <sup>(2)</sup>:

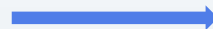
- household appliances intended for domestic use,
- audio and video equipment,
- information technology equipment,
- ordinary office machinery,
- low-voltage switchgear and control gear,
- electric motors;



(p) the following electrical and electronic products, insofar as they fall within the scope of Directive 2014/35/EU or of Directive 2014/53/EU:

- (i) household appliances intended for domestic use which are not electrically operated furniture;
- (ii) audio and video equipment;
- (iii) information technology equipment;
- (iv) ordinary office machinery **except additive printing machinery for producing three-dimensional products;**
- (v) low-voltage switchgear and control gear;
- (vi) electric motors;

— motor vehicles and their trailers covered by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers <sup>(1)</sup>, with the exclusion of machinery mounted on these vehicles,



(g) motor vehicles and their trailers, **as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, which fall within the scope of Regulation (EU) 2018/858, except for machinery mounted on those vehicles;**

# Machinery Regulation 2023/1230

## Definitions

Definition of machinery remains the same with one addition:

(f) an assembly as referred to in points (a) to (e) missing only the uploading of the software intended for the specific application foreseen by the manufacturer;

Clarification of existing definitions:

(b) 'interchangeable equipment' means a device which, after the putting into service of machinery or of a tractor is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;

(2) 'interchangeable equipment' means a device which, after the putting into service of machinery or an agricultural or forestry tractor is assembled with that machinery or agricultural or forestry tractor by the operator in order to change its function or to attribute a new function to it, provided that the device is not a tool;

Expansion of existing definitions:

(c) 'safety component' means a component:

- which serves to fulfil a safety function,
- which is independently placed on the market,
- the failure and/or malfunction of which endangers the safety of persons, and
- which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

(3) 'safety component' means a physical or digital component, including software, of a product within the scope of this Regulation, which is designed or intended to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endanger the safety of persons, but which is not necessary in order for that product to function or for which normal components may be substituted in order for that product to function;



# Machinery Regulation 2023/1230

## Definitions

### New Definitions Added:

- Safety function
- Making available on the market
- Essential health and safety requirements
- Union harmonisation legislation
- Substantial modification
- Instructions for use
- Importer
- Distributor
- Economic operator
- Technical specification
- CE marking
- Accreditation
- National accreditation body
- Conformity assessment body
- Notified body
- Market surveillance authority
- Recall
- Withdrawal
- Lifetime
- Source code
- Professional user

# Machinery Regulation 2023/1230

## EHSRs

### Annex Structure Modified:

#### Part A: Definitions

All definitions remain the same as per 2006/42/EC with the exception of the term Machinery being replaced by Machinery and related products.

#### Part B: General Requirements

No-longer the option for the authorised representative to carry out the risk assessment.

New chapter defining the risk assessment requirements more clearly.

New chapter stating the risk assessment requirement applies also to partly completed machinery.

### EHSRs:

All the EHSR numbers are aligned between 2006/42/EC and 2023/1230, except for 1.7.4.3 (sales literature) ⇒ 1.75.

#### New EHSRs added:

- 1.1.9 Protection against corruption.
- 2.4 Machinery or related products for plant protection products application.
- 3.2.4 Supervisory function (relating to autonomous mobile machinery).
- 3.6.3.3 Information and indications – instructions for use – Autonomous mobile machinery

# Machinery Regulation 2023/1230

## Conformity Assessment Procedures

### Machinery Directive 2006/42/EC

Non Annex IV Machinery:  
Assessment of Conformity with internal checks

Annex IV Machinery + conformity with harmonised standards, one of the following:

- Assessment of Conformity with internal checks
- Assessment of Conformity with internal checks + EC Type examination
- Full quality assurance procedure.

Annex IV Machinery not in accordance with harmonised standards, one of the following:

- Assessment of Conformity with internal checks + EC Type examination
- Full quality assurance procedure.

### Machinery Regulation 2023/1230

Non Annex I Machinery:  
Assessment of Conformity with internal checks

Annex I, Part B machinery or related products, one of the following:

- Conformity to type based on internal production control (c) (only if in accordance with Harmonised standards)
- EU Type examination (B) + Conformity to type based on internal production control (c)
- Full quality assurance (H)
- Unit verification (G)

Annex I, Part A machinery or related products, one of the following:

- EU Type examination (B) + Conformity to type based on internal production control (c)
- Full quality assurance (H)
- Unit verification (G)

# Machinery Regulation 2023/1230

## Instructions

- Art. 10(7) 'The instructions may be provided in a digital format'
- EHSR 1.7.4.1 requirement to mark 'original instructions' or 'translation of original instructions' has gone.
- The EU declaration doesn't have to be in the instructions, instead an internet address or machine readable code can be used.
- (v) Additional content requirement: information on the necessary precautions, devices and means of immediate and gentle rescue of persons.
- (u) Additional content requirements: relating to airborne noise emissions
- (X) Additional content requirement: to detail what is required to capture, filter or discharge any emissions of hazardous substances

# Machinery Regulation 2023/1230

## Declaration of Conformity

### EU declaration of conformity of machinery and related products No ... <sup>(1)</sup>

The EU declaration of conformity shall contain the following particulars:

1. The machinery or related product (product, type, model, batch or serial number) or substantially modified machinery or related product.
2. Name and address of the manufacturer and, where applicable, its authorised representative.
3. For lifting machinery which is intended to be permanently installed in a building or a structure and which cannot be assembled in the manufacturer's premises but can only be assembled at the place of use, the address of that place.
4. This declaration of conformity is issued under the sole responsibility of the manufacturer.
5. Object of the declaration (identification of the machinery or related product allowing traceability; where necessary for the identification of the machinery or related product, a colour image of sufficient clarity may be included).

# Machinery Regulation 2023/1230

## Declaration of Conformity

6. The object of the declaration referred to in point 5 is in conformity with the following Union harmonisation legislation.

7. References to the harmonised standards referred to in Article 20(1) or common specifications adopted by the Commission in accordance with Article 20(3) that were applied, including the date of the publication of the reference to harmonised standards in the *Official Journal of the European Union* or of the common specification, or references to the other technical specifications, including their date, in relation to which conformity is declared. In the event of partial application of harmonised standards or common specifications, the EU declaration of conformity shall specify the parts which were applied.

8. Where applicable, the notified body ... (name, number) ... performed the EU type-examination (Module B) and issued the EU type-examination certificate ... (reference to that certificate), followed by conformity to type based on internal production control (module C) or the conformity based on unit verification (module G) or full quality assurance (module H).

9. Where applicable, the machinery or related product is subject to the conformity assessment procedure based on internal production control (Module A).

10. Additional information:

Signed for and on behalf of: ...

(place and date of issue):

(name, function) (signature):

Trying to keep on top of **it all...**

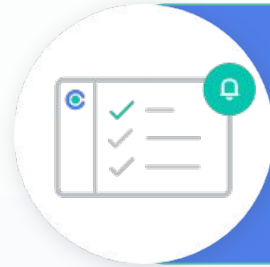


# A Smarter Way to Manage Product Compliance

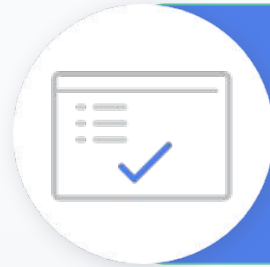
Holistic Market Access Solutions



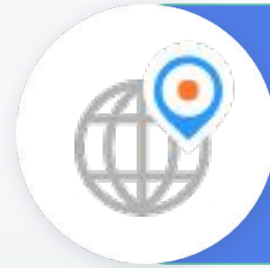
# Unlock Market Access, by ...



Demonstrating Compliance



For what is required



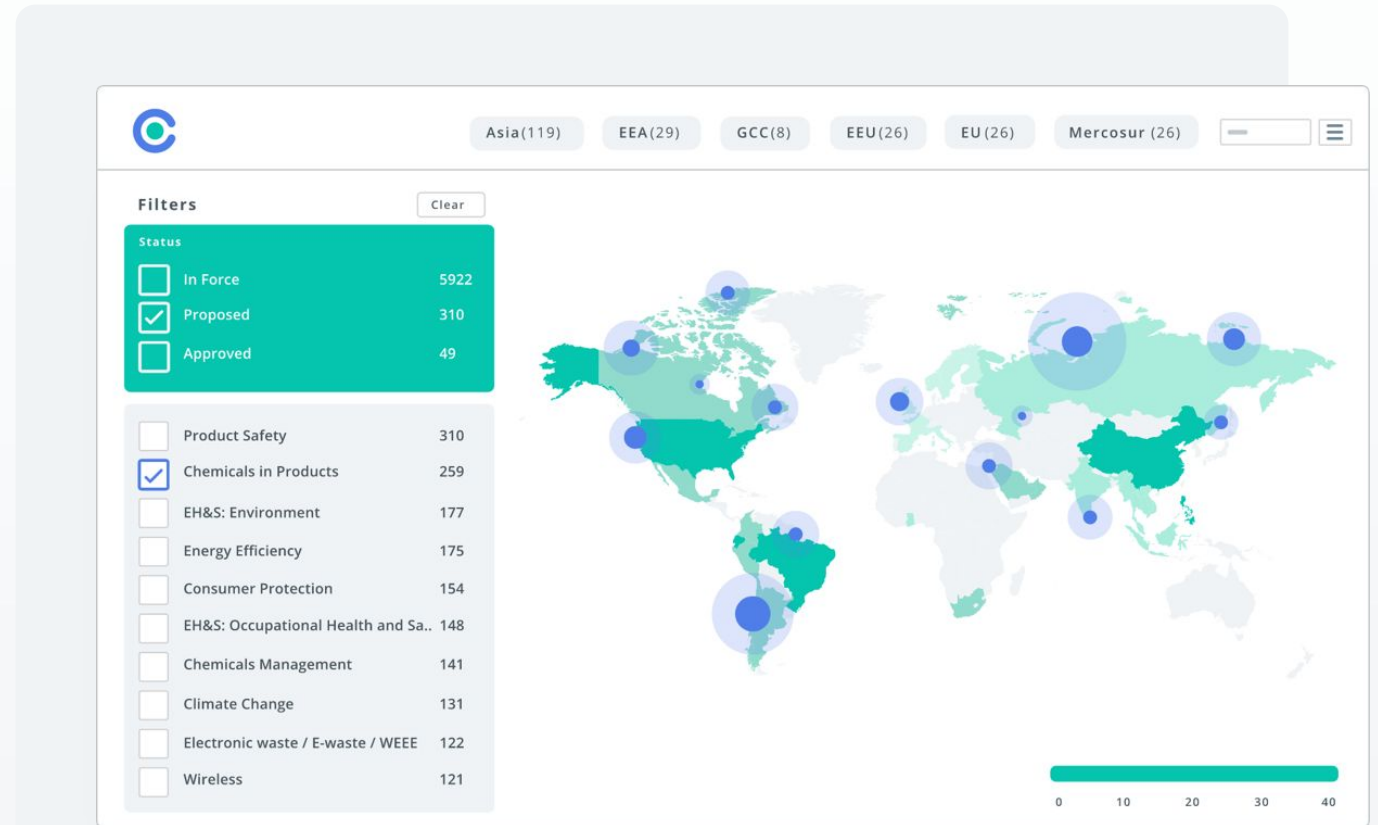
Driven by Global  
Regulations & Standards

TECHNOLOGY - C2P

# C2P

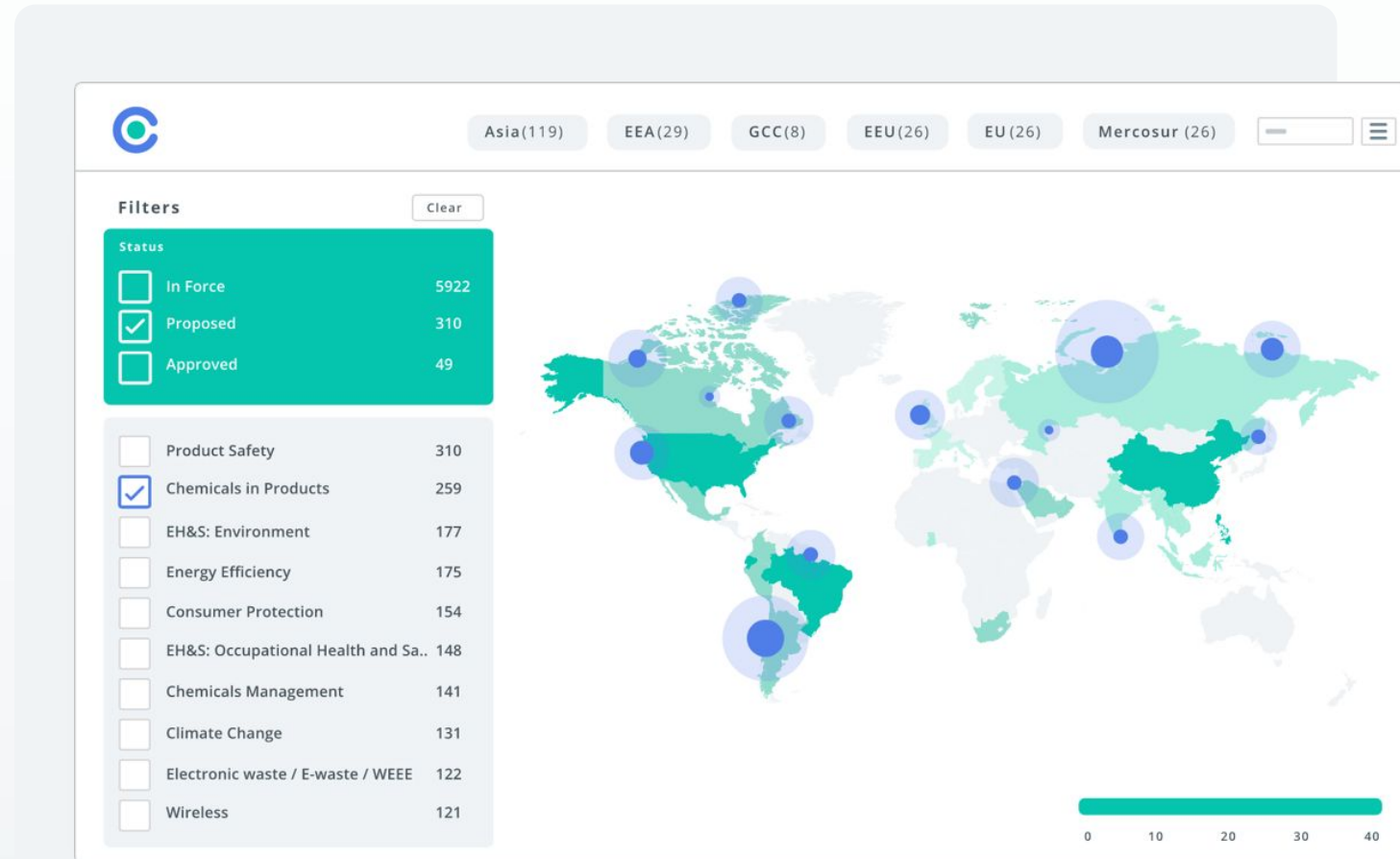
## The Key to Unlocking Market Access

- Enterprise grade technology
- Cloud based platform
- Access to regulatory coverage in 195 countries
- Heatmaps with what's hot & where
- Intelligent search
- AI powered probability analysis
- Productivity tools to improve team collaboration



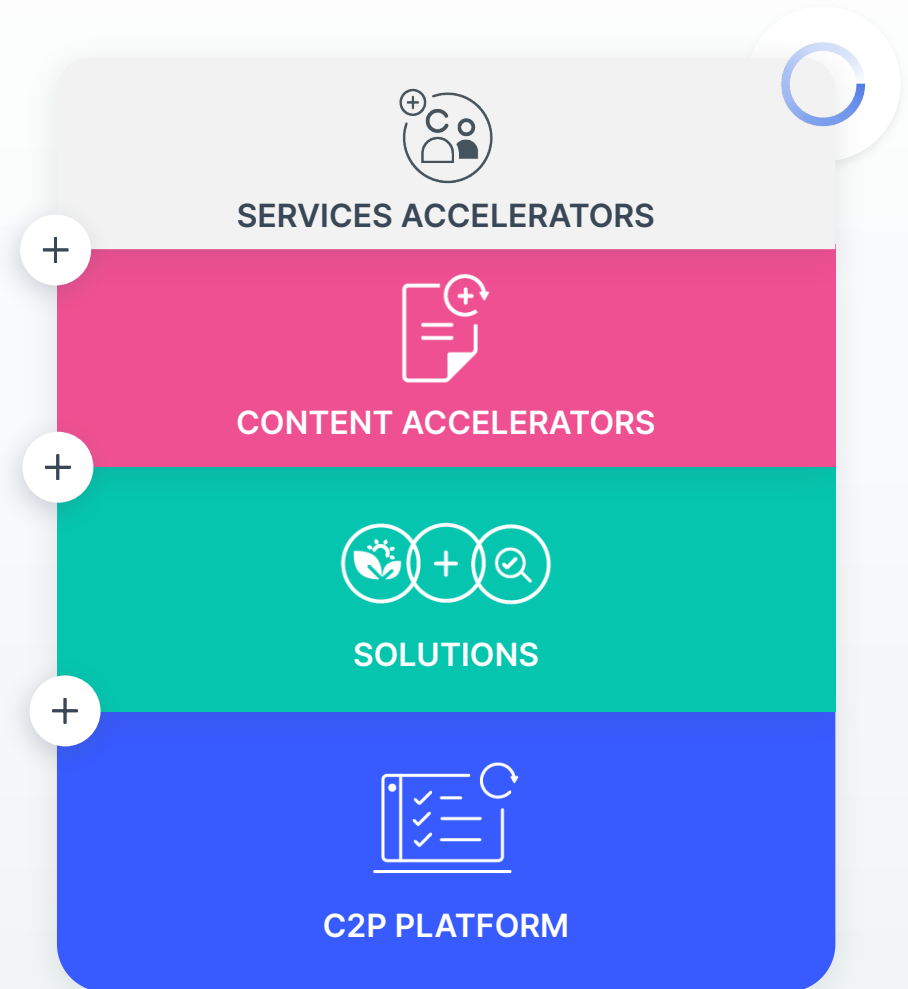
# Manage everything in One Place...

- Design, build, and collaborate on new products with confidence
- Keep all compliance evidence up to date & live linked back to their Regulations, Standards & Requirements
- Continually monitor regulatory changes & keep ahead of proposed changes before they happen
- Integrate with other systems to enable streamlined business processes



# Tailored to meet your needs...

- Comprehensive capabilities that enable enterprise-wide management of regulations, standards, requirements and evidence
- Add-on packages to accelerate market access through:
  - Use-case specific solutions
  - Global regulatory content
  - Professional services



# Q&A

# Thank you!



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