

WHITE PAPER

NOVEL AI-BASED MACHINERY CERTIFICATION METHODOLOGY



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INDEX



0

INTRODUCTION

- **Industry 5.0 and the Evolving Role of Humans in Manufacturing** **Page 3**
- **Regulatory Challenges: Adapting the Machinery Framework to Industry 5.0** **Page 4**
- **Scope and Purpose of This White Paper** **Page 4**

1

MACHINERY DIRECTIVE 2006/42/EC

- **A historical perspective** **Pages 5-6**

2

AI AND DATA GOVERNANCE

- **The rise of artificial intelligence, data governance and AI Act Directive** **Pages 7-9**

3

THE NEW MACHINERY REGULATION 2023/1230

- **Addressing the gaps** **Pages 10-12**

4

THE PENELOPE VISION

- **Our position** **Pages 13-25**

5

A HUMAN FUTURE OF WORK

- **Final remarks** **Page 26**

Industry 5.0 and the Evolving Role of Humans in Manufacturing

Over the past few decades, industrial automation has significantly reshaped manufacturing and labour through the introduction of advanced technologies. In recent years, the European manufacturing landscape has undergone a transformative shift, moving beyond efficient, automated, and data-driven production toward a more human-centric, resilient, and sustainable model—a transition known as the Industry 5.0 paradigm.

Industry 5.0 defines the human worker as a pivotal element in production. This paradigm leverages technology to enhance human capabilities rather than replace them, fostering an environment where humans and machines collaborate seamlessly.

This transformation is driven by the adoption of collaborative robots (cobots), exoskeletons, and AI, emphasizing cooperation over full automation. Rather than isolating workers from machinery, Industry 5.0 promotes direct human-machine interaction, where industrial equipment is designed to augment human skills, reduce physical strain, and create safer, more adaptive workspaces.

While this paradigm shift offers significant benefits—enhanced worker safety, increased productivity, and improved well-being—it also introduces new challenges in industrial production. As cobots, exoskeletons, and AI-driven systems become integral to workplaces, ensuring their certification for industrial use is critical. These technologies must comply with rigorous safety standards, risk assessment protocols, and regulatory frameworks to guarantee that human workers remain protected in increasingly complex industrial environments.

Authors

Félix Vidal (1), Afra M. Pertusa (1), Ana Rodríguez (1), Christian Precker (1), Daniella B. Deutz (2), Valerio Bracchi (3), Ander Martin Rebe (4), Mariluz Penalva (4), Zoi Arkouli (5), Mihail Babcsinchi (6), Pedro Neto (6).

(1) Asociación de Investigación Metalúrgica del Noroeste (AIMEN), Porriño, 36410, Spain.

(2) Royal Netherlands Aerospace Centre (NLR), AVTH, Voorsterweg 31, 8316 PR Marknesse, The Netherlands

(3) RINA Consulting S.p.A., Palazzo R, Strada 7, Via Gran S. Bernardo, 20089 Rozzano MI, Italy

(4) TECNALIA, Basque Research and Technology Alliance (BRTA), Parque Científico y Tecnológico de Guipúzcoa, 20009, Donostia-San Sebastián, Spain

(5) Laboratory for Manufacturing Systems & Automation, University of Patras, Rion Patras, 26504, Greece

(6) Department of Mechanical Engineering, University of Coimbra, Coimbra, Portugal



Augmented and virtual operator



Super-strong operator



Social and collaborative operator



Healthy and happy operator



One-of-a-kind operator



Regulatory Challenges: Adapting the Machinery Framework to Industry 5.0

The European Union's Machinery Directive 2006/42/EC was a milestone in regulating industrial machinery safety, primarily designed for traditional, standalone machines operating in controlled environments. However, the emergence of Industry 5.0 presents unprecedented regulatory challenges that go beyond the scope of conventional machinery.

Key concerns include:

- **AI-Driven Decision-Making:** How should risk assessments be conducted? How can autonomous decision-making in collaborative robotics be made transparent, predictable, and safe?
- **Wearable Industrial Equipment:** Traditional safety requirements focus on machinery operating independently, but exoskeletons and AI-driven wearables redefine the boundary between human and machine. How should safety certification be adapted to account for machines integrated into the worker's body?
- **Worker Autonomy vs. Automation:** How can regulations ensure that human workers remain in control of AI-enhanced production rather than becoming subordinate to algorithmic decision-making?
- **Cybersecurity and Ethical AI:** As industrial equipment becomes increasingly connected through the Internet of Things (IoT) and AI, how can regulations address the risks of cybersecurity breaches, AI biases, and data privacy concerns in human-machine collaboration?

The Purpose of This White Paper

This white paper critically examines the new Machinery Regulation 2023/1230, particularly its enhanced focus on worker safety, health, and well-being in the context of Industry 5.0 technologies. It will explore the evolving concepts of autonomy, collaboration, and human-machine synergy, analysing how regulations must evolve to balance technological innovation with human-centred safeguards.

Ultimately, this paper advocates for an evaluation of the human role in industrial production, asserting that workers must remain central to manufacturing, not passive operators in an increasingly automated system. While Industry 5.0 offers the potential for a more inclusive, efficient, and sustainable workforce, its success depends on ensuring that technological advancements empower, rather than displace, human workers.

MACHINERY DIRECTIVE 2006/42/EC:

The Machinery Directive 2006/42/EC, first adopted by the European Union, has served as a cornerstone in regulating the safety of industrial machinery. Its primary objective is to establish an harmonise legislation of the Member States in order to ensure a standard of health and safety for operators, users, and even the general public, covering a broad spectrum of machinery, from small hand tools to large industrial machines. By setting essential safety requirements, the directive ensures that machinery is safe to operate, minimizes risks to workers, and complies within European market standards.

The directive applies to the following types of products: Machinery; ii) Interchangeable equipment; iii) Safety components; iv) Lifting accessories; iv) Removable mechanical transmission devices; v) Ropes, webbing and chains and vi) Partly completed machinery. In this context, machine builders, assemblers of machine parts or installations, manufacturers of special-purpose tools, skids and rigs or machinery importers located in the EU are responsible for the compliance with the machinery directive. In addition, machinery distributors or dealers that buy from the EU-based manufacturer or importer have the obligation to verify that the conformity assessment was performed and that the necessary documentation and information is available.

The compliance process of any machinery should include the following steps: i) Determining the applicable essential health and safety requirements from the directive and from related harmonised standards; ii) Conformity assessment by ensuring that the product satisfies all essential health and safety requirements applicable to it; iii) Compiling into a Technical File the set of technical documentation proving the machinery's compliance with the requirements; iv) Drawing up an EU Declaration of Conformity and ensure that it accompanies the product; v) Affixing the CE marking to the product, vi) Taking steps to ensure the machinery remains in compliance, even after modifications and after amendments of the regulations and standards.

The conformity assessment process under the Machinery Directive 2006/42/EC is a crucial procedure that ensures machinery meets the essential health and safety requirements before being placed on the European market. In standard machines the manufacturer can conduct a self-assessment by preparing a technical file and issuing a Declaration of Conformity. This means the manufacturer takes full responsibility for compliance without needing external certification. However, for high-risk machinery, the manufacturer can self-certified if the machinery fully complies with harmonized European standards. If not, an independent, accredited certification organization must evaluate the machine's design, construction, and testing.

While the Machinery Directive 2006/42/EC has been highly effective in ensuring safety in traditional machinery, the rapid technological advancements of Industry 4.0 and Industry 5.0 have created new challenges. Key areas requiring updated regulatory frameworks include:

- Artificial Intelligence (AI) – The directive does not fully address AI-based decision-making, machine learning, or autonomous safety controls.
- Collaborative Robots (Cobots) – Current regulations lack clarity on human-robot interaction safety and real-time machine adaptability.
- Exoskeletons and Wearable Machinery – These devices directly interact with human bodies, requiring specialized safety protocols beyond traditional machine guidelines.
- Cybersecurity and Connected Systems – The directive does not sufficiently cover risks associated with Industrial IoT (IIoT), remote access vulnerabilities, or cyber-physical attacks.
- Digital Documentation and Paperless Compliance – The traditional requirement for paper manuals is outdated in an era of digital interfaces and dynamic machine learning algorithms.

Recognizing these gaps, the European Union has adopted the Machinery Regulation 2023/1230, which will replace the 2006 directive and introduce comprehensive updates to address AI, robotics, cybersecurity, and human-machine collaboration. This new regulation ensures uniform implementation across all EU Member States by eliminating national transpositions and providing a future-proof safety framework for modern industrial automation.

The evolution from directive to regulation marks a fundamental shift in how machinery safety is governed, promoting continuous innovation, stricter cybersecurity measures, and clear AI governance in the manufacturing sector.

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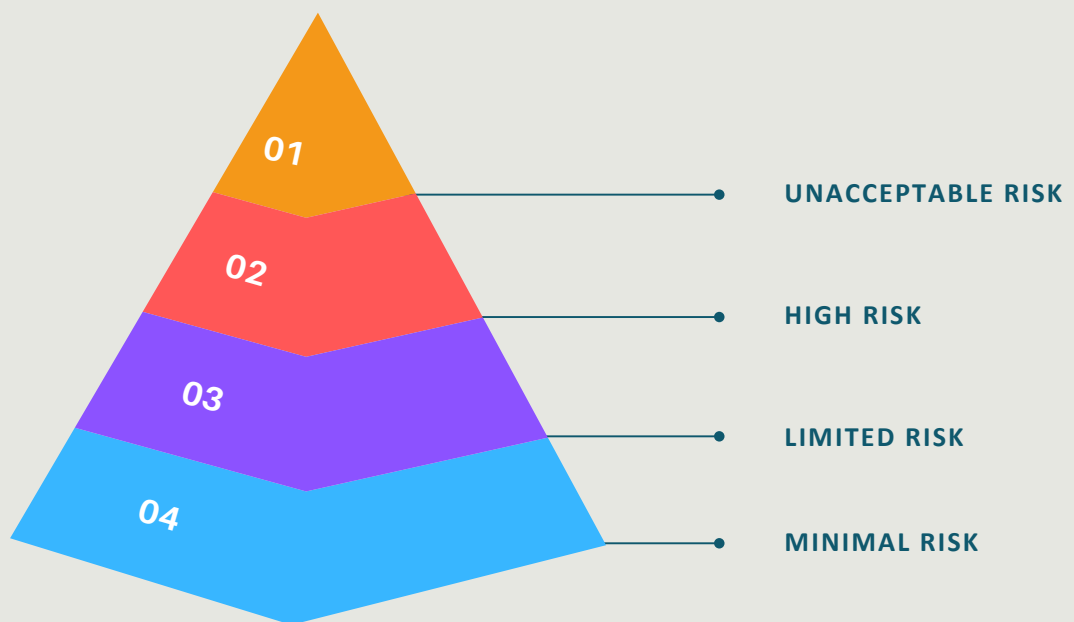
THE RISE OF ARTIFICIAL INTELLIGENCE, DATA GOVERNANCE AND AI ACT DIRECTIVE

Artificial Intelligence and Data Governance

Artificial intelligence (AI) is revolutionizing the relationship between technology and society, with significant implications for the coexistence of humans and machines. The impact of this interaction spans economic, social, and ethical dimensions. From an economic perspective, AI offers opportunities for automation and optimization of processes, enhancing efficiency, sustainability and accuracy.

In April 2021, the European Commission proposed the first EU artificial intelligence law, establishing a risk-based AI classification system. AI systems that can be used in different applications are analysed and classified according to the risk they pose to users. The different risk levels mean more or less AI compliance requirements. In June 2024, the EU adopted the world's first rules on AI. The Artificial Intelligence Act (Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence) is the first-ever comprehensive legal framework on AI worldwide. The aim of the rules is to foster trustworthy AI in Europe. The AI Act sets out a clear set of risk-based rules for AI developers and deployers regarding specific uses of AI. The AI Act is part of a wider package of policy measures to support the development of trustworthy AI. These measures guarantee safety, fundamental rights and human-centric AI, and strengthen uptake, investment and innovation in AI across the EU.

The AI Act defines 4 levels of risk for AI systems:



Unacceptable risk

All AI systems considered a clear threat to the safety, livelihoods and rights of people are banned. The AI Act prohibits eight practices, namely:

1. Cognitive behavioural manipulation of people or specific vulnerable groups: for example, voice-activated toys that encourage dangerous behaviour in children
2. Social scoring AI: classifying people based on behaviour, socio-economic status or personal characteristics
3. Biometric identification and categorisation of people
4. Real-time and remote biometric identification systems, such as facial recognition in public spaces

High risk

AI systems that negatively affect safety or fundamental rights will be considered high risk and will be divided into two categories:

1. AI systems that are used in products falling under the EU's product safety legislation. This includes industrial equipment, aviation, cars, medical devices and lifts.
2. AI systems falling into specific areas that will have to be registered in an EU database:
 - o Management and operation of critical infrastructure
 - o Education and vocational training
 - o Employment, worker management and access to self-employment
 - o Access to and enjoyment of essential private services and public services and benefits
 - o Law enforcement
 - o Migration, asylum and border control management
 - o Assistance in legal interpretation and application of the law.

All high-risk AI systems will be assessed before being put on the market and also throughout their lifecycle. including: i) adequate risk assessment and mitigation systems; ii) high-quality of the datasets feeding the system to minimise risks of discriminatory outcomes; iii) logging of activity to ensure traceability of results; iv) detailed documentation providing all information necessary on the system and its purpose for authorities to assess its compliance; v) clear and adequate information to the deployer; vi) appropriate human oversight measures; vii) high level of robustness, cybersecurity and accuracy.

A regulatory conformity assessment process should be required if we need to put on the market these type of AI systems.

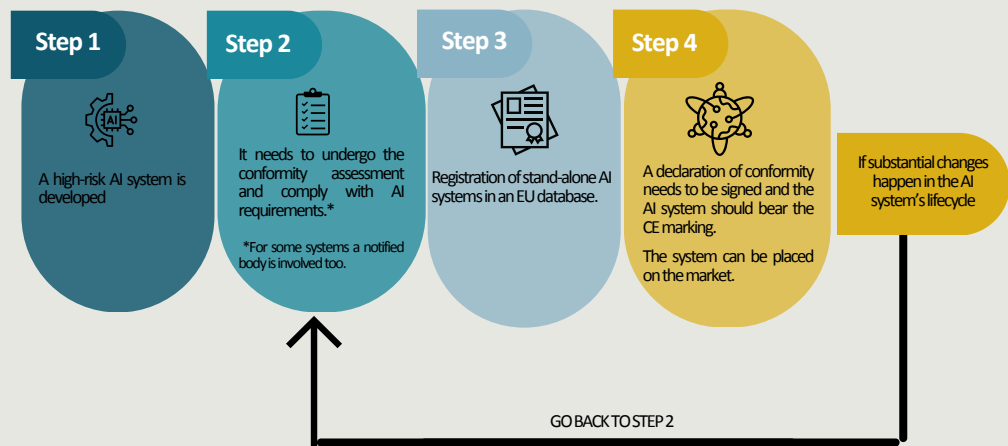


Figure 3. Conformity assessment process for high-risk AI systems.

Transparency risk

This refers to the risks associated with a need for transparency around the use of AI. The AI Act introduces specific disclosure obligations to ensure that humans are informed when necessary to preserve trust. For instance, when using AI systems such as chatbots, humans should be made aware that they are interacting with a machine so they can take an informed decision.

General-purpose AI models can perform a wide range of tasks and are becoming the basis for many AI systems in the EU. Some of these models could carry systemic risks if they are very capable or widely used. To ensure safe and trustworthy AI, the AI Act puts in place rules for providers of such models. This includes transparency and copyright-related rules. For models that may carry systemic risks, providers should assess and mitigate these risks.

Minimal or no risk

The AI Act does not introduce rules for AI that is deemed minimal or no risk. The majority of AI systems currently used in the EU fall into this category. This includes applications such as AI-enabled video games or spam filters. Nevertheless, AI applications in manufacturing are not in this category.

Encouraging AI innovation and start-ups in Europe

The law aims to support AI innovation and start-ups in Europe, allowing companies to develop and test general-purpose AI models before public release. That is why it requires that national authorities provide companies with a testing environment for AI that simulates conditions close to the real world. This will help small and medium-sized enterprises (SMEs) compete in the growing EU artificial intelligence market, and worldwide.

The AI Act entered into force on 1 August 2024, and will be fully applicable 2 years later on 2 August 2026, with some exceptions:

- prohibitions and AI literacy obligations entered into application from 2 February 2025
- the governance rules and the obligations for general-purpose AI models become applicable on 2 August 2025
- the rules for high-risk AI systems - embedded into regulated products - have an extended transition period until 2 August 2027

3

THE NEW MACHINERY REGULATION 2023/1230

Addressing the Gaps

The AI act introduces new concepts related with the use of AI systems and AI-powered equipment. This machinery must comply novel conformity assessment procedure to guarantee the AI and machinery safety. In this context, to complement the AI Act directive, the Machinery Regulation 2023/1230 was introduced in June 2023 to address the technological advances derived from the use of AI in industrial equipment, particularly in areas involving robotics, AI, and automated systems by defining safety measures to be guaranteed when human and machine interacts.

The Machinery Regulation 2023/1230 was introduced as a comprehensive update to replace the Machinery Directive 2006/42/EC to align with AI advancements, ensuring that AI-integrated machinery is covered under new risk assessment and cybersecurity provisions, by assessing the mechanical and operational safety of machinery using AI. This results in the definition and implementation of the safety standards not only to machinery and related products, but also to software. From January 20, 2027, the CE marking of machinery or assessment of partly completed machinery will be mandatory under the Machinery Regulation EU 2023/1230.

The list of products in Annex VI of Machinery Directive 2006/42/EC has been updated in Annex I of Machinery Directive 2023/1230/EC by specifying a list of high-risk machines, for which mandatory inspection and certification through a third party is required. As a result, higher risk machinery is now divided into two categories (Figure 4):

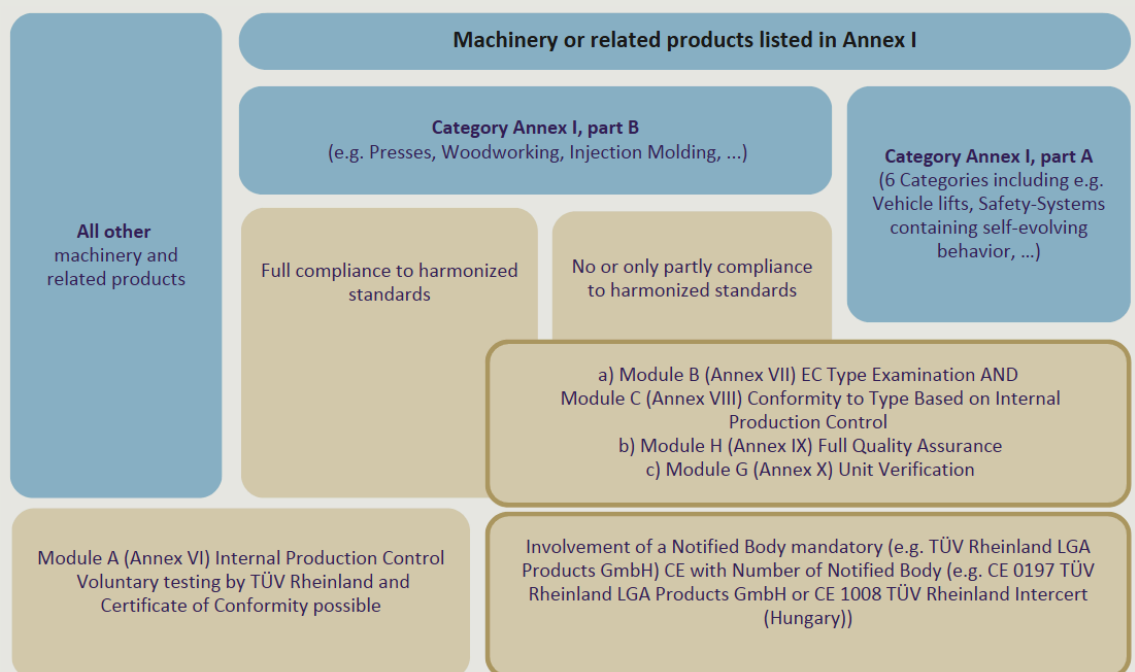


Figure 4. High-risk machinery certification assessment process. Source: TÜV Rheinland.

Machinery with behaviour that can be modified by self-learning mechanisms, including i) Removable mechanical transmission devices including their guards; ii) Guards for removable mechanical transmission devices; iii) Vehicle servicing lifts; iv) Portable cartridge-operated fixing and other impact machinery; v) Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions; vi) Machinery that has embedded systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems.

In these machine types, machine manufacturers alone can no longer declare conformity in conjunction with a harmonised standard, as it was previously possible in the Machinery Directive. In future, a notified body must be involved. This is necessary in part due to the reference to artificial intelligence. This type of machinery always requires the involvement of a notified body. It can either certify the machine itself through an EU type-examination or certify the underlying quality assurance system prior to the actual production of the machine. However, where machinery embeds a system of which the safety component has already been subject to third party conformity assessment when it was placed independently on the market, that machinery should not have to be re-certified by a third party solely on the basis of the embedding of that system.

For example, systems with self-evolving behaviour ensuring safety functions should require novel conformity assessment process due to their characteristics such as data dependency, opacity, autonomy and connectivity, which might considerably increase the probability and severity of harm and seriously affect the safety of the machinery or related product. Therefore, the conformity assessment of a safety component or a system with self-evolving behaviour ensuring safety functions should be carried out by a third party, whether or not the safety component has been placed independently on the market or is part of a system embedded in machinery that is placed on the market.

Other categories of machinery, including i) Circular saws; ii) Hand-fed surface planing machinery for woodworking; iii) Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking; iv) Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics; v) Combined machinery of previous equipment for working with wood and material with similar physical characteristics; vi) Hand-fed tenoning machinery with several tool holders for woodworking; vii) Hand-fed vertical spindle moulding machinery for working with wood and material; viii) Portable chainsaws for woodworking; ix) Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading; x) Injection or compression plastics-moulding machinery; xi) Injection or compression rubber-moulding machinery; xii) Machinery for underground working of the following types: locomotives and brake-vans;

hydraulic-powered roof supports; xiii) Manually loaded trucks for the collection of household refuse incorporating a compression mechanism; xiv) Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than 3 m; xv) Protective devices designed to detect the presence of persons; xvi) Power-operated interlocking movable guards designed to be used as safeguards in machinery; xvii) Logic units to ensure safety functions; xviii) Roll-over protective structures; xix) Falling-object protective structures.

In these machine types, the machine manufacturer themselves can still declare conformity with the Machinery Regulation in combination with a harmonised standard, with the aid of internal production control. However, if there are no harmonised standards available, or they are not enough to cover all aspects of the machine, or if the manufacturer wishes to knowingly deviate from these standards, the involvement of a notified body is required.

The EU Machinery Regulation also takes up the new subject of “security”. Machinery and related products that have been certified or for which a statement of conformity has been issued under a cybersecurity certification scheme adopted in accordance with Regulation (EU) 2019/881, as regards protection against corruption and safety and reliability of control systems insofar as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.

Manufacturers shall ensure that the machinery or related products are accompanied by the instructions for use and technical documentation, such as machinery description, risk assessment, drawings and schemes, harmonised standards, design calculation, tests, inspection, the source code or programming logic of the safety related software to demonstrate the conformity of the machinery. The instructions may be provided in a digital format. Such instructions and information shall clearly describe the product model to which they correspond. When the instructions for use are provided in digital format, the manufacturer shall (a) mark on the machinery or related product, or, where that is not possible, on its packaging or in an accompanying document, how to access the digital instructions; (b) present them in a format that makes it possible for the user to print and download the instructions for use and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machinery or related product; this requirement also applies where the instructions for use are embedded in the software of the machinery or related product; (c) make them accessible online during the expected lifetime of the machinery or related product and for at least 10 years after the placing on the market of the machinery or related product.

Bridging the gaps by addressing digitalisation and AI

Machinery Regulation (EU) 2023/1230 updated safety requirements by incorporating digital and cybersecurity aspects, specially by the introduction of specific safety requirements for machines with self-learning capabilities or remote updates, as well as by including cybersecurity measures to prevent hacking and software manipulation.

4

THE PENELOPE VISION

Our position

PENELOPE represents a significant step forward in the advancement of large-scale, one-of-a-kind manufacturing across various industries, including aerospace, shipbuilding, transport, and energy. PENELOPE project develops a methodology linking product-centric data management, production planning and scheduling in a closed-loop digital pipeline. The aim is to ensure accurate and precise manufacturability from the initial product design. A key aspect of PENELOPE is its emphasis on worker-centric solutions, ensuring that human skills remain central to manufacturing processes while benefiting from digital advancements (Industry 5.0 paradigm). The integration of VR/AR applications, collaborative robotics, and digital assistance tools enhances worker productivity, safety, and quality. These solutions empower employees by reducing physical strain, providing real-time guidance, and preserving their industry knowledge and skills. In this approach, PENELOPE leverages data-driven methodologies and AI-powered equipment across various application categories, further advancing the efficiency, precision and flexibility of the portfolio of solutions to meet the demands and needs required in the manufacturing of large components.

WORKER-CENTRIC ROBOTICS AND DIGITAL INTERFACES

Robotics Systems and Wearables for Minimizing Exposure to Ergonomic Risks

PENELOPE introduced robotic and wearable technologies to support operators in physically demanding tasks in large-large part manufacturing including tasks involving heavy components, non-ergonomic movements, or extended reach (Figure 5). These systems have been designed to reduce exposure to ergonomics risks while allowing operators to remain directly involved in production and transmit skills to robots, in line with Industry 5.0 principles. A portfolio of robotics systems including collaborative mobile robots, high-payload collaborative robotic arms, cable robots, and collaborative mobile platforms were deployed in use cases demonstrating their capacity to perform precision tasks such as gluing, assembly, inspection, and material handling, while reducing operator fatigue, improving accessibility in large workspaces, and supporting safe human-robot collaboration without the need for physical barriers.

The robotic systems were enhanced with inline sensing to enable process adaptation and robot teaching by demonstration. For instance, the development of perception modules for part detection, pose estimation, and real-time robot path adjustment. The Trajectory Manager Software, which supports runtime modification of robot paths and simulation-based validation, complemented the portfolio of solutions. The software is intended for non-expert users and aligns with emerging requirements for operator oversight and editable automation under the AI Act.



Figure 5. Robotic and wearable technologies supporting workers in physically demanding tasks in the manufacturing and assembly of large-scale components.

Knowledge Transfer & Operator Empowerment Solutions

To support skill retention, reduce training time, and improve operator performance in complex or variable production tasks, PENELOPE developed a set of AR/VR-based tools and digital interfaces focused on guided execution, remote support, and immersive training (Figure 6). These tools address mental workload and cognitive strain in labour-intensive processes, allowing operators to access real-time information, standard operating procedures, and expert feedback without interrupting the task flow.

AR modules provide step-by-step instructions, QA checklists, and visual cues through wearable devices (HoloLens, Realwear), enabling consistent task execution and fast onboarding. The same platform integrates defect documentation, inspection guidance, and ad-hoc support features for in-situ quality control and repair.

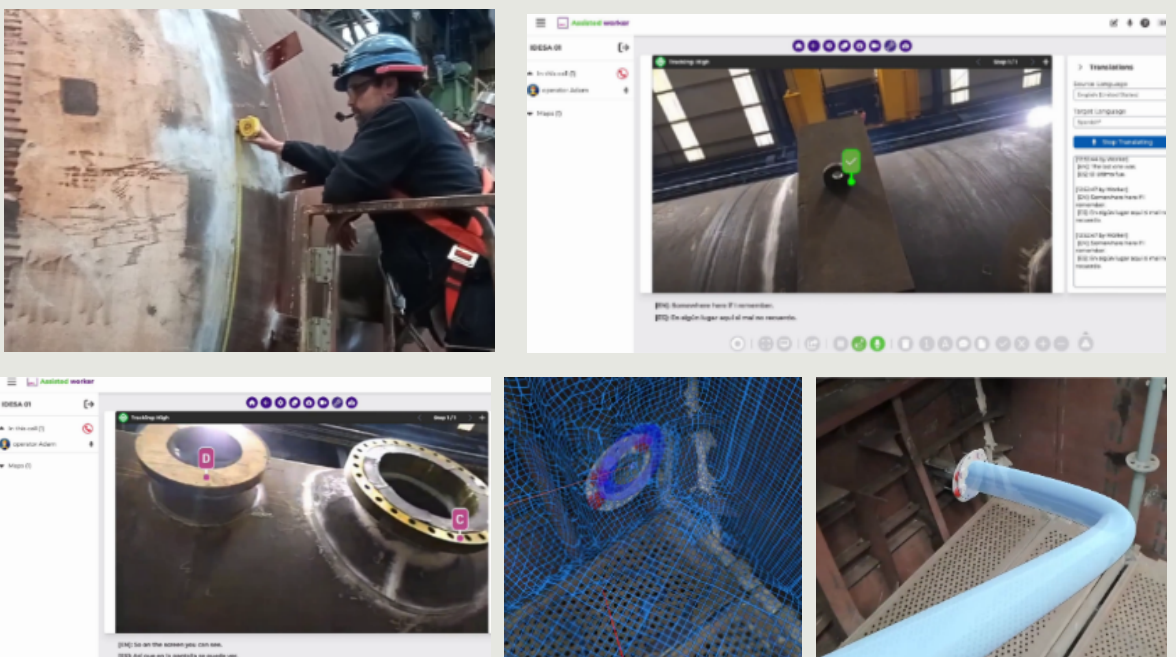


Figure 6. AR tools used for remote and step-by-step guidance.

The VR Training environments (Figure 7) allow safe familiarisation with robot operations, workspace layout, and task execution procedures, especially in scenarios where errors are costly or first-time right performance is required. These systems include real-time metrics, interactive task flows, and scenario-based training logic to accelerate learning curves without interrupting production.



Figure 7. VR tools for immersive training.

Complementary tools such as the manufacturing status verification module and a tool for tracing (Figure 8) on large components based on AR principles assisted in ensuring traceability of process execution and enabled informed decision-making during production, even in low-connectivity environments.



Figure 8. Adaptive projection for insite tracing of auxiliary elements in large components.

Collectively, these solutions reduce the need for formal training, standardise knowledge transfer, and enable scalable deployment of new processes with minimal ramp-up time.

Human-Centric Programming & Interaction Supporting Human Acceptance and Control

To support the integration of robotics in production without excluding operators from process control, PENELOPE introduced a set of programming and interaction tools that minimise technical barriers and promote operator acceptance. These developments focus on intuitive task definition, hands-on robot programming, and accessible control interfaces, in line with the AI Act principles for transparency, explainability, and human oversight.

Zero-programming approaches (Figure 9) were implemented to generate robot trajectories from scanned geometries or point clouds, without requiring manual coding. These systems were applied to additive post-processing and NDT scenarios, using CAD alignment and automated motion planning pipelines.



Figure 9. Zero programming solutions developed in PENELOPE.

A mimic-based programming framework that captures expert manufacturing skills through demonstration and converts them into executable robot programs. This allows experienced operators to transfer process knowledge without needing robotics expertise.

Hand-guiding solutions allow direct physical interaction with robotic arms, supporting both kinesthetic teaching and co-manipulation of large parts. These interfaces were tested on high-payload robots and validated in production tasks.

AR-based programming tools complement these developments by enabling spatial definition of robot paths using gesture and voice commands, reducing programming time and improving user comprehension. Additional modules Trajectory Manager and HMI/HRI Launcher provide simulation, runtime path editing, and user-friendly interfaces for interaction with robot controllers.

These tools enable non-experts to configure and adapt robotic systems locally, without dependence on offline programmers, supporting flexible deployment in high-mix, low-volume environments.

Speed and Separation Monitoring

Speed and Separation Monitoring (SSM) is a safety technology based on artificial vision. In the vision system we detect the presence and body pose of the operators inside the robot working area. Taking into account the real-time position of the robot and the pose and position of the operator, distance between worker and robot is computed in the way we dynamically can adapt robot speed going through three possible states: normal, reduced and stop, following the flow shown in Figure 10. For people detection and people tracking module, the system applies the YOLOv8 to detect them in each of the cameras of the stereo deployed solution (Figure 11).

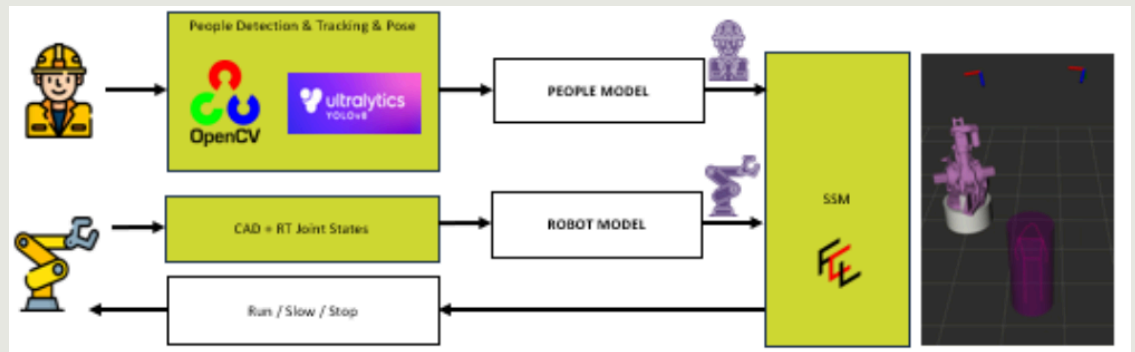


Figure 10. SSM dataflow.

Therefore, in the machinery classification classes (Figure 4) we could fit this solution in Annex I by specifying a list of high risk machines in the categories: Machinery with behaviour that can be modified by self-learning mechanisms (safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions) and Other categories of machinery (protective devices designed to detect the presence of persons). To certify the systems and ensure operator safety when interacting with the robotic system, we can rely on:

- Collision models and parametrisation
- AI trust
- Hacking possibilities

To consider the safety measures and fulfil with the certification normative, SSM considers a collision model for the operator, which means that we approximate the detected person to a cylinder bigger than operator dimensions, so that we can cover the possible detection errors or accuracy that are inherent to the vision system. Furthermore, distances in which the robot needs for stopping, reducing or reestablishing the speed can be manually adjusted so we can easily increase them to adapt safety margins. For sending commands to the robot, we are always considering the most restrictive action (stop over reduced, and reduced over normal), as the window of time we are considering in order to avoid flickering data.

- Besides, the use the Artificial Intelligence YOLO algorithm allows us to easily upgrade the system with new YOLO versions that are more robust, increasing the trust of the safety system, as this is a public neural network.

(1) [YOLOv8: State-of-the-Art Computer Vision Model](#)



Figure 11. YOLOv8 tracking in stereo system.

In terms of the hacking possibilities, problem may come from the connection to the network of the devices so, once the weights of the neural network are downloaded, we could manage communications between robot, cameras and processing computer locally in an isolated network, so that the system is not exposed to vulnerabilities.

Additionally, a step towards the increase of SSM trust will be launching another neural network for people detection in parallel to mitigate situations in which the operator may not be detected due to occlusions with the robot or external components or stereo mismatching. If this is still giving some misdetections of the operator, we could consider deploying this solution with some ultra-wideband (UWB) tags or another classical safety methods.

Another source of error may be the calibration accuracy that it is around 5 cm for 2 m of distance between the camera and the robot reference system, that we avoid partially with the collision models. A different error that is added to the system is the accuracy of YOLOv8 for people detection and pose detection. The SSM requires an initial people detection for then extracting the pose and compute the distances between the different agents of the scene. Therefore, we must take into account the accuracy of both detections, which have been evaluated in the following links:

- People detection benchmarking: [Detector - Ultralytics YOLO Docs](#)
- Pose detection benchmarking: [Pose - Ultralytics YOLO Docs](#)

PENELOPE tested and deployed the SSM solution in cells equipped with different robots: ABB, KUKA and UR with the cameras placed in areas with the smaller number of possible occlusions, to ensure optimal workspace coverage. Nevertheless, we have observed that, when the working area has many elements, we cannot cover the area with a unique stereo pair, so it is needed to increase the cameras in the scene. In Figure 12, SSM is represented for a KUKA robot in the PENELOPE supply-tray demonstrator.

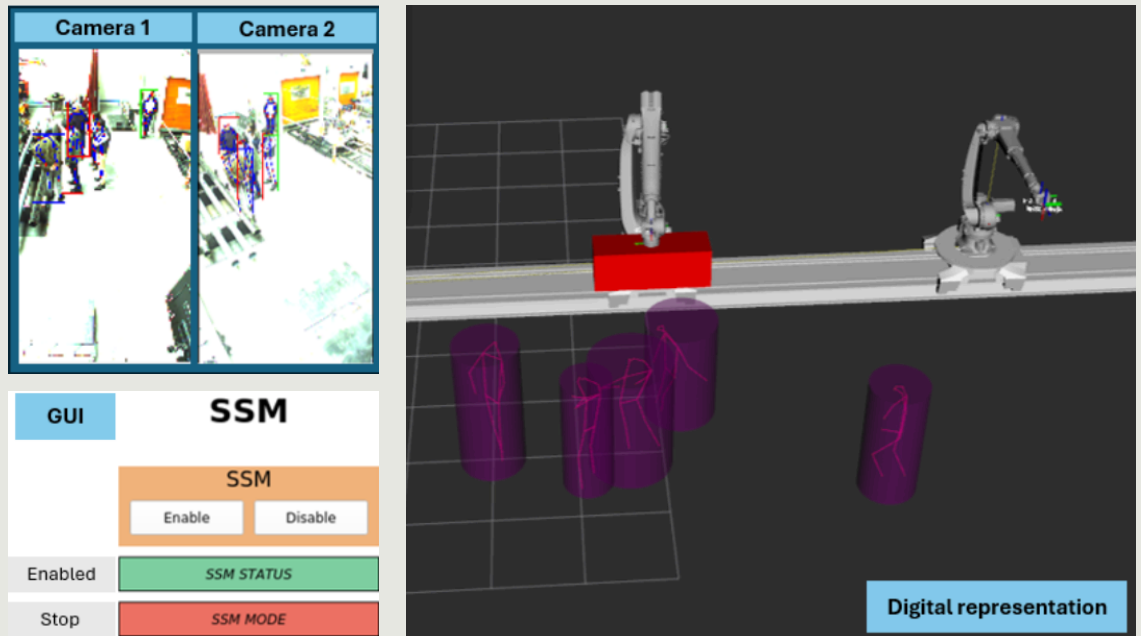


Figure 12. SSM working. Stop situation.

As a conclusion, current safety standards for collaborative robotics, along with broader machine directives (e.g., ISO/TS 15066, Machinery Directive 2006/42/EC), ensure human safety. Nevertheless, companies face significant barriers to deploying collaborative robot technologies due to regulatory constraints. While these directives are essential, they must be continuously updated to keep pace with technological advancements and the growing complexity of robotic systems featuring embedded AI. There is a need for specific regulatory frameworks that allow innovative companies to test emerging technologies at early stages within the European Union. This can be done by creating innovative testing clusters where companies can safely test and advance their technologies, enabling the certification of the entire robotic system, including those with AI components and human-in-the-loop interaction, rather than certifying AI algorithms in isolation. In such contexts, safety regulations are expected to evolve more rapidly, drawing on real-world experiences of using robots in shared environments, interacting with multiple users, and operating across diverse industrial and service settings. This is a balanced approach, allowing for controlled experimentation and gradual adoption, while still maintaining safety standards.

QUALITY ASSURANCE TOOLS

AI-Driven Tools for Submerged Arc Welding

The integration of artificial intelligence (AI) in industrial processes is redefining the standards of quality assurance in Submerged Arc Welding (SAW). In the context of Industry 5.0, AI-powered quality assurance tools are not just designed to detect defects but to enhance operator decision-making, predict failures, and ensure regulatory compliance. As AI-driven machines shift towards self-adaptation, regulatory bodies, including those enforcing EC Machinery Regulation 2023/1230, require AI-powered systems to be certified through third-party notified bodies rather than self-certification.

A critical aspect of AI integration in SAW processes is the self-diagnosing capability, where machines continuously assess welding conditions, predict defects, and suggest corrective actions in real time. These AI systems must provide traceable, explainable, and auditable records that can be assessed by certification authorities. Ensuring compliance means AI-driven welding solutions must not only enhance welding performance but also provide transparent insights into their decision-making process, reinforcing the role of human oversight rather than replacing it.

AI-powered self-diagnostic modules within SAW must incorporate real-time monitoring, predictive analysis, and adaptive process control. These modules analyze welding data streams, detect irregularities, and adjust process parameters accordingly. The ability to identify defects before they fully develop and adjust welding parameters dynamically ensures compliance with ISO quality standards and aligns with Industry 5.0's human-centric approach.

Four key AI-driven methodologies were implemented in the context of PENELOPE's project to enhance quality assurance in SAW welding: RCNN-based defect detection, LSTM autoencoders for anomaly detection, computer vision techniques using YOLOv8, and 3D profilometry for weld reconstruction.

First, a RCNN-based defect detection model, which combines Convolutional Neural Networks (CNNs) for feature extraction and Long Short-Term Memory (LSTM) networks was used for sequential pattern analysis. This hybrid model enables real-time detection of porosity defects within SAW welding processes, see Figure 13 (a). By continuously analyzing welding voltage and current fluctuations, the system identifies surface porosity at early stages, achieving 80% detection accuracy while maintaining a processing time of less than 10 milliseconds. This capability is essential for real-time inline quality monitoring, allowing immediate intervention before defects compromise weld integrity. Furthermore, by providing a detailed defect history, the model enhances traceability and compliance with AI transparency standards, ensuring auditability for notified bodies.

The second AI model applied in SAW was the LSTM autoencoder (LSTM-AE) for anomaly detection, which was trained exclusively on high-quality welds to learn their normal electrical behavior. By identifying deviations from expected patterns in voltage and current signals, the system can detect anomalous conditions that may indicate imminent defects, see Figure 13 (b). This approach supports predictive maintenance strategies, preventing defective welds before they occur. The model enhances safety-critical AI classification, ensuring that welding operations comply with ISO machine safety standards and AI transparency requirements outlined in EC Machinery Regulation 2023/1230. Additionally, its ability to detect irregularities in real-time facilitates certification by notified bodies, ensuring compliance with evolving AI regulations.

To address visual inspection challenges, AI-powered computer vision systems using YOLOv8 (You Only Look Once version 8) enable automated defect detection in welding images and videos. AIMEN trained a model to identify welding imperfections such as porosity, achieving a detection precision of over 80%, see Figure 13 (c). With real-time image processing capabilities, the model can analyze live video feeds, assisting human operators in making informed quality decisions. Unlike traditional visual inspections that rely on subjective human judgment, the YOLOv8 model ensures consistent, traceable, and explainable defect detection, aligning with ISO 3834 (welding quality) and EN 17637 (visual inspection of welds) standards. By incorporating AI-enhanced non-destructive testing (NDT) capabilities, it strengthens compliance with certification requirements for automated welding quality control.

Finally, and in addition to detecting individual defects, maintaining geometric integrity in SAW welding is crucial. 3D profilometry for weld reconstruction enables a comprehensive analysis of weld bead geometry, ensuring compliance with ISO geometric tolerances. Using profilometer data, a system that reconstructs weld profiles in three dimensions has been developed, allowing for the detection of misaligned beads, uneven weld thickness, and surface deformations, see Figure 13 (d). This method supports predictive maintenance strategies, allowing manufacturers to monitor plate deformation and welding deviations over time. As AI-driven welding moves toward digital twin integration, 3D profilometry provides the necessary data for real-time virtual modeling, ensuring compliance with EC Machinery Regulation 2023/1230 by offering a traceable, data-driven approach to certification.

As AI-driven SAW systems become standard in modern manufacturing, certification frameworks must evolve to accommodate self-diagnosing AI systems. Under EC Machinery Regulation 2023/1230, AI-powered welding machines must be certified by a notified body through either EU type-examination or quality assurance system certification before production. Ensuring compliance requires AI models to provide auditable decision logs, real-time monitoring capabilities, and integration with human operators.

To comply with these requirements, AI models used in SAW welding must undergo third-party assessment to validate defect detection accuracy, anomaly recognition reliability, and process stability. AI systems must demonstrate explainability and reproducibility, ensuring that defect detection and anomaly recognition processes are traceable and certifiable. Additionally, notified bodies must establish AI-specific auditing protocols to validate adaptive AI-driven systems that modify their behavior based on real-time data inputs.

A major component of certification is the EU type-examination process, where AI-based welding systems undergo extensive performance validation before market approval. AI-powered quality assurance tools must pass reliability assessments, ensuring that models maintain consistent performance under various welding conditions. This includes testing how AI responds to welding parameter fluctuations, different material compositions, and environmental variations. Only after passing these assessments can AI-powered welding machines receive regulatory certification.

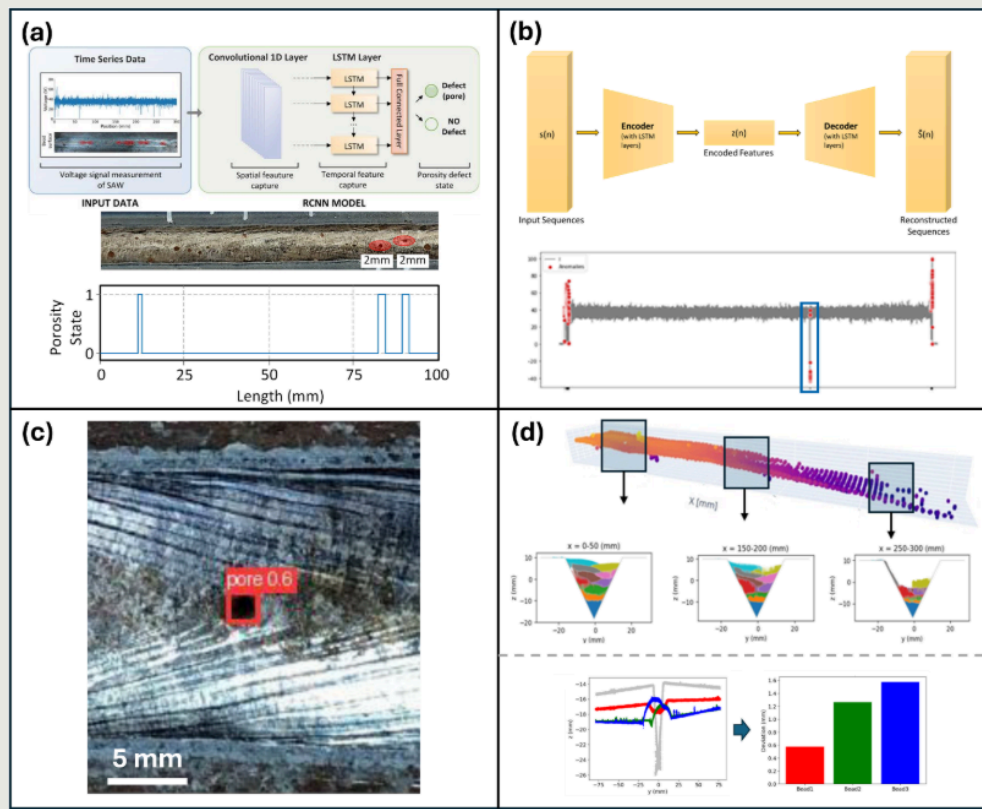


Figure 13. (a) The General Architecture of the RCNN Model, and porosity detection on a test weld segment, see the two red highlighted regions showing 2 pores with 2 mm diameter, and below the two blue peaks indicating the model detection of them. (b) LSTM-AE network diagram, and anomaly detection in voltage signal indicated by the red dots inside the blue box. (c) Weld bead surface showing a pore detected at its centre by a trained YOLOv8 trained model. (d) Profilometer data acquired from the surface of weld beads along a welded coupon. The profile of the beads can be seen along the whole weld, specified by the x coordinate for the length, y for the width, and z by the depth. During each weld bead is possible to see the plate deformation, where the light-grey lines indicates the coupon before welding, red after the first bead passed, green after the second, and blue after a third bead. The deformation is clearly visible comparing the horizontal lines that represents the coupon's surface.

For manufacturers integrating AI into welding, an alternative pathway is quality assurance system certification, where the manufacturing process itself is assessed rather than individual machines. This approach ensures that AI models used for quality assurance and predictive defect detection meet harmonized industry standards, such as ISO 3834 for fusion welding and ISO 12100 for machine safety. By certifying the quality management process, manufacturers can streamline AI-powered production while maintaining compliance with evolving AI regulations.

To ensure that AI-powered SAW quality assurance tools comply with regulatory requirements, manufacturers must align their AI models with harmonized industry standards. Compliance with ISO 3834 guarantees that AI-enhanced welding quality control meets internationally recognized benchmarks. Similarly, adherence to EN ISO 17636-2 ensures AI-based defect detection aligns with non-destructive testing methodologies, while ISO/IEC 42001 provides governance structures for AI system management. Compliance with ISO 12100 further ensures AI-powered systems meet machine safety risk assessment criteria, reinforcing the regulatory legitimacy of self-adaptive welding machines.

By integrating AI-driven self-diagnostic capabilities, real-time monitoring, and predictive maintenance into SAW processes, manufacturers can meet certification requirements while enhancing welding precision, defect prevention, and regulatory transparency. As AI-powered quality assurance becomes integral to welding automation, adopting a standardized certification framework will be essential to ensuring safe, reliable, and regulation-compliant Industry 5.0 manufacturing.

Fast NDT inspection of carbon fibre-reinforced composites

Current quality assurance systems in aeronautics are based on ultrasonic testing. Current ultrasonic testing of large parts takes a lot of time. In PENELOPE, alternative, faster non-destructive inspection methods such as thermography, shearography, and direct velocity mapping (DVM), have therefore been investigated on their suitability for detection of defects in CFRP panels for aircraft. Though the testing phase of these methods is faster than ultrasonic testing, the interpretation of the test results with these methods still requires a lot of time. Therefore, faster interpretation of thermographic test results of large CFRP panels was investigated in PENELOPE.

The goal of the AI-driven defect recognition tools is to assist (Industry 5.0 paradigm) the thermographic inspection experts by providing them automatically with the most relevant thermographic scans, enhanced with indications about potential defects, thus enhancing worker productivity and quality. With this drastic reduction of information compared to the full set of available non-interpreted scans, the thermographic inspection expert can rapidly:

- check their agreement on the automatically detected potential defects,
- classify potential defects,
- initiate further appropriate actions to handle these potential defects, and
- provide feedback to the production line.

with the ultimate goal to quickly avoid further defects due to the same cause in the next large parts that are produced.

These methods can be used to reduce the workload for the current quality assurance systems in aeronautics. However, before such AI-driven digital assistance tools can be implemented, they must first be qualified and certified for aeronautics, meeting the relevant acceptance criteria.

DATA-DRIVEN MODELS FOR OPTIMISING MANUFACTURING STRATEGIES

The ability of AI to learn from historical data, either real or from simulation tools, enabled workers to define optimal manufacturing parameters. Within the PENELOPE project, a decision support system for the optimisation of roll forming and surrogate models of squeezing were developed to support and optimise the design of gluing processes.

Decision Support Systems (DSS) are revolutionizing the manufacturing industry by enhancing decision-making processes for factory workers. A notable development achieved in PENELOPE project is the application of DSS in the rolling of large and thick plates into cans, commonly used to fabricate pipes or tanks. Traditionally, this process relied heavily on trial and error, requiring significant operator intervention and resulting in a high variability of the final products.

The proposed DSS solution prescribes optimal process parameters for operators, significantly reducing the need for trial and error. This advancement not only minimizes the time and number of passes required for the first-of-a-kind parts but also enhances overall efficiency. The development of this DSS involved several critical steps, including signal preprocessing and classification, followed by data extraction, aggregation, and regression within a multi-stage prediction framework. The substantial use of domain knowledge ensures high-quality recommendations and facilitates the transfer of know-how among operators.

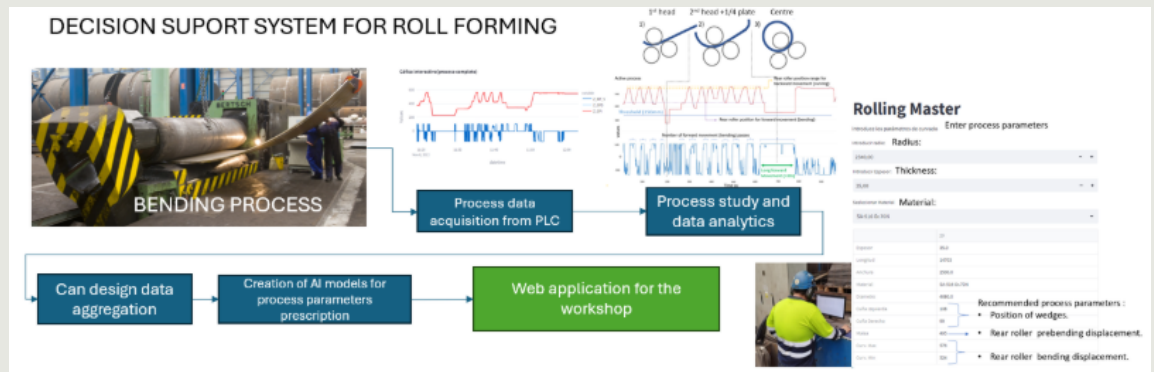


Figure 14. DSS development flow chart with process, data visualization and HMI pictures.

The new Machinery Regulation (EU) 2023/1230 introduces stricter safety and conformity assessment requirements, which will significantly impact the certification of high-risk machinery, such as roll forming machines. Although the Decision Support System (DSS) suggests process parameters to be applied by the machine operator, the machine itself remains under the control of an expert human. In this scenario, self-learning mechanisms do not automatically modify the machinery's behavior; instead, the worker applies the suggested parameters manually. Therefore, the DSS operates externally to the machine, affecting only the design of the process parameters without altering the machine's use. Further research and developments could integrate this kind of developments in new machines.

Under the new regulation, manufacturers must ensure that their DSS-equipped machinery complies with updated safety standards and undergoes rigorous conformity assessments. This includes verifying that the DSS recommendations enhance safety and efficiency without compromising the operator's control over the machine. Additionally, the regulation mandates the inclusion of cybersecurity measures to protect against potential threats, further influencing the certification process. These updates aim to ensure that advanced machinery, such as roll forming machines with DSS, meets the highest safety and performance standards before entering the market.

Another development of the PENELOPE project is the surrogated model to assess gluing design by optimizing the squeezing process. It is a significant advancement in the automated design of parameters for glue application processes through the efficient use of physics-based numerical simulation. By employing a meta-modeling approach that integrates numerical simulation with artificial intelligence techniques, process parameters can be precisely designed.

In this development, a simulation of the glue squeezing process was used to create a set of synthetic data, which was subsequently expanded using augmentation techniques. Metamodeling was then applied to develop a model that correlates glue application parameters with the features of the glued area. This model can either directly infer the features of the glued area based on selected process parameters or be used in conjunction with an optimization algorithm to determine the most suitable process parameters. Furthermore, based on the model predictions, additional information of interest from a production perspective, such as operation time and glue expenditure, can be calculated.

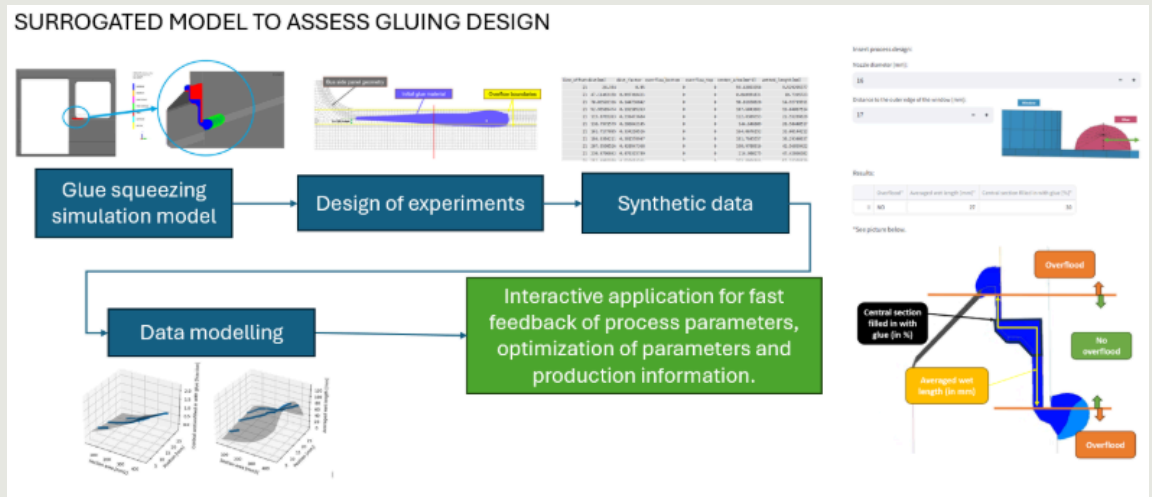


Figure 15. Surrogated model development flow chart with simulation, data generation, modelling and HMI pictures.

In this case again, the development optimizes process parameters, but it is not integrated in any machine or tool. Results must be interpreted by human experts. Therefore, the new machinery regulation 2023/1230 does not imply new requirements in terms of machine certification with respect to the Machinery Directive 2006/42/EC. However, the AI Act directive applies to all AI systems, whether developed, deployed, or used within the EU, regardless of their origin. Providers of AI systems have to ensure that AI systems are designed and developed with safety and security by design principles, provide transparent and explainable AI systems, implement robust testing and validation procedures and establish incident reporting mechanisms.

According to the EU AI Act these developments are high risk. High-risk AI systems are subject to stricter requirements, including third-party audits and certification, continuous monitoring and evaluation, human oversight and review.

5

A HUMAN FUTURE OF WORK

Final Remarks

The transition from traditional automation to Industry 5.0 requires a fundamental redefinition of human-machine collaboration in industrial workspaces. The integration of AI, collaborative robotics, wearable machines, together with advanced digital tools enhances efficiency, flexibility, and productivity, but also imposes new responsibilities on manufacturers, developers, and regulators.

The adoption of the new Machinery Regulation 2023/1230 and the AI Act (2024/1689) highlights the EU's commitment to position Europe to play a leading role globally by redefining safety and compliance standards in the industrial sector, raising awareness of new technologies. These initiatives ensure that high-risk AI systems, including adaptive robots, wearable machinery, and autonomous quality assurance tools meet robust requirements for transparency and explainability, human oversight, cybersecurity, and safety. Compliance with the new Machinery Regulation and the AI Act becomes essential for all companies in the industrial sector. These new regulations represent important advancements towards a safer and more technologically advanced industrial environment, in which the workforce roles must evolve, with the workers remaining pivotal in decision-making, supported by AI.

In this context, the PENELOPE project demonstrates how Industry 5.0 principles can be operationalized in real-world manufacturing environments through several and complementary industrial-driven pilot lines. Through a worker-centric, data-driven methodology, PENELOPE has shown how the implementation of digital technologies—from collaborative robotics to AI-based welding and inspection systems—should improve accuracy, productivity, safety, and quality in the assembly and manufacturing of large components.

Key examples of the PENELOPE project include:

- Development of worker-centric robotics and digital interfaces relying on perception and inline sensing to enable process adaptation, ensuring worker safety in dynamic robotic environments.
- Integration of self-diagnosing AI modules in Submerged Arc Welding, aligning with third-party certification requirements under the new Machinery Regulation.
- Deployment of AI-assisted thermographic analysis for CFRP panel inspection, increasing speed and accuracy in aerospace quality assurance.
- Implementation of Decision Support Systems and surrogate models to optimize manufacturing strategies, balancing machine intelligence with human oversight.

By addressing both the technological and regulatory dimensions of Industry 5.0, PENELOPE has laid a foundational framework for safe, scalable, and certifiable AI-powered manufacturing in different high-value sectors.