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Complete compliance when exporting machinery to the EU

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Machine builders exporting to the European Union should already be aware of the need for CE marking to the Machinery Directive 2006/42/EC. However, recent years have seen several other pieces of EU legislation come into force that machine builders might be less familiar with. This article summarises the current EU legislative requirements, though machine builders need to check which ones apply to them.

Machinery Directive

First of all, the Machinery Directive requires machinery to be CE marked. The process is straightforward, yet it needs to be undertaken rigorously:

- Conduct a formal risk assessment so the risks can be designed-out and reduced as necessary;
- Design and manufacture the machine so it complies with the essential health and safety requirements (applying harmonised standards is usually the easiest way to do this);
- Ensure the manufacturing process has a suitable quality assurance system;
- Prepare the user instructions;
- Compile the technical file;
- Arrange a third-party assessment by an EU Notified Body if the machine is of a type that requires it;
- Prepare an EC Declaration of Conformity (DoC), noting that non-EU machine builders must name someone established in the EU who is authorised to compile the technical file; and
- Affix the CE mark.

The Machinery Directive is currently the main piece of legislation that must be complied with. In January 2027, when it is replaced by the Machinery Regulation (EU) 2023/1230, the basic procedure for CE marking will remain the same but there are some additional requirements:

- Measures must be in place to ensure the cyber-security of safety-related control systems; and
- Consideration must be given to ensure machinery is safe if artificial intelligence is used (see also the AI Act below).
- The Declaration becomes an EU Declaration, with different wording requirements.

EMC

Machinery often incorporates electrical equipment that has the potential to cause electromagnetic interference and/or be disturbed by external emissions. If this is the case, then the machinery also needs to be CE marked to the Electromagnetic Compatibility (EMC) Directive 2014/30/EU. The CE marking process is similar to that for the Machinery Directive and can be summarised as:

- Take appropriate steps during the design phase to avoid EMC-related problems where possible;
- Conduct EMC testing in-house or at an EMC test laboratory;
- Compile the technical documentation;
- Prepare an EU Declaration of Conformity (DoC); and
- Affix the CE mark.

Radio Equipment Directive

If a machine incorporates equipment that emits or receives radio signals for communication purposes, then it could fall within the scope of the Radio Equipment Directive 2014/53/EU, commonly referred to as the RED. This includes technologies such as WiFi, Bluetooth, LTE, 5G, GPS and RFID (but not passive tags). CE marking to the RED proceeds as follows:

- Design the product in accordance with relevant harmonised standards or, if not, use other means to ensure the RED essential requirements are met;
- Depending on the nature of the product and whether harmonised standards have been applied, the manufacturer may be able to self-certify or, if not, third-party laboratory testing and/or EU-type examination by a Notified Body may be necessary;
- Compile the technical documentation;
- Prepare an EU Declaration of Conformity (DoC); and
- Affix the CE mark (which could be to the radio equipment, packaging or instructions, depending on the product).

The European Commission's official guide to the RED states that radio equipment falling under the scope of the RED is excluded from both the LVD and EMC Directive, though the RED does refer to the essential requirements for these two Directives. Furthermore, a machine builder can give precedence to the Machinery Directive if the machine incorporates radio equipment.

Authorised representatives

Another important piece of legislation is Regulation 2019/1020 on market surveillance and compliance. This prohibits goods from being placed on the market unless there is an 'economic operator' established in the EU. Economic operators are responsible for ensuring conformity documentation is available, co-operating with market surveillance authorities and informing authorities if a product presents a risk.

Non-EU manufacturers can appoint an economic operator that is an importer, authorised representative or fulfilment service provider. For machinery, an authorised representative (usually shortened to AR or EUAR) is likely to be the only viable option. If a machine builder appoints an AR to act on its behalf in accordance with the Regulation, the AR can be a natural or legal person established in the EU who has a written mandate to do so. Note that the AR should be competent to understand the Machinery Directive conformity documentation, ensure it is fit for purpose, and be ready to respond to enquiries from EU market surveillance authorities.

Ecodesign

Regulation (EU) 2019/1781 lays down ecodesign requirements for electric motors and variable speed drives (VSDs) and has been in force since 2021. Compared with the similar Regulation it replaced, 2019/1781 broadens the scope to include smaller motors of 0.12 to 0.75kW, larger motors of 375 to 1000kW, 60Hz motors, eight-pole motors and single-phase motors of 0.12kW or above. In addition, the Regulation introduced efficiency requirements for VSDs rated at 0.12 to 1000kW.

If machines incorporate motors or drives that fall within the scope, then a copy of the motor/VSD data sheet or manual must be supplied with the machine's documentation and a copy must be retained. If the machine builder is not established in the EU, and has therefore appointed a person who is authorised to compile the technical file and an AR (see above), then it would be logical for that person to retain the motor/VSD documentation alongside the other documentation.

Batteries

Machines might incorporate various types of battery, such as 'portable batteries for general use' (ie button cells, D, C and AA batteries, etc), industrial batteries, or batteries used in uninterruptible power supplies. All of these fall within the scope of Regulation (EU) 2023/1542 that has applied since 2024. In the eyes of this legislation (often referred to as the EU Battery Regulation or EU BR), incorporating batteries makes machine builders 'producers' and they have obligations that can be summarised as below:

- The machine builder must register with the competent authority in each member state where its machines are sold;
- A declaration of conformity (DoC) must be drawn up and translated into the language of each member state in which machines are sold (NB this may be incorporated within the Machinery Directive DoC);
- Rechargeable industrial batteries with a capacity greater than 2 kWh must be accompanied by a document stating certain performance and durability parameters;
- If a machine incorporates portable batteries, the machine must be accompanied by instructions and safety information relating to the batteries' use, removal and replacement (and the same information must also be available on a website);
- Machine builders must have a take back and collection system, though most will meet this obligation by joining a producer responsibility organisation (PRO);

- Regardless of whether a machine builder joins a PRO, they must report annually on the numbers of batteries sold and collected, and what happened to them; and
- Non-EU producers must appoint an EU Authorised Representative (AR) who must be mandated to perform certain tasks on their behalf.

Note that additional documentation requirements come into force between 2026 and 2029, so machine builders should begin preparing for these.

Artificial intelligence

With today's widespread adoption of artificial intelligence (AI), this technology is finding applications within machinery for tasks such as predictive maintenance and control systems. While there is currently no equivalent in the UK, the EU has legislated so as to promote the uptake of AI that is human-centric and trustworthy. If a machine incorporates AI and is placed on the market in the EU, then it must comply with the Artificial Intelligence Regulation (EU) 2024/1689, often referred to as the AI Act, which entered into force in August 2024.

Several categories of AI system are defined in the AI Act. For machine builders, the category of interest is high-risk AI systems used as safety components. Such systems were due to be regulated and require CE marking from 2 August 2027 but, at the time of writing, it is looking likely that this will be delayed by a year because of a delay in preparing the necessary harmonised standards.

CE marking to the AI Act follows a process similar to that for the Machinery and EMC Directives:

- Design the AI system to meet the AI Act's requirements (the easiest way to demonstrate compliance should be to apply harmonised standards, though these have not yet been published);
- Ensure there is an approved quality management system for the design, development and testing of the AI system;
- Compile the technical documentation;
- Prepare an EU Declaration of Conformity (DoC);
- Affix the CE mark (if a physical CE mark cannot be applied, the CE mark can be shown on packaging, accompanying documentation, or a digital CE mark can be applied);
- Non-EU producers must appoint an EU Authorised Representative (AR) who must be mandated to perform certain tasks on their behalf; and
- Undertake post-market monitoring for the system's lifetime and, if any serious incidents occur, report them to the relevant market surveillance authority.

EU Data Act

Most recently, Regulation (EU) 2023/2854 has come into force, covering harmonised rules on fair access to and use of data. This legislation, often referred to as the EU Data Act, has significant implications for many machine builders.

In simple terms, if a machine stores data relating to its operation and use, and if the machine builder can access that data either remotely or by connecting to the machine locally, then the data must be sharable. As well as the machine user being able to access the data, the user can also require that access be given to a third party. In certain circumstances, the authorities can also demand access to data.

From the perspective of a non-EU machine builder exporting to the EU, complying with the Data Act requires the following unless there are relevant exemptions:

- Certain information about the data and its usability must be made available before a sale, lease or rental contract is concluded;
- There must be an agreement with the data user regarding which data is sharable, the characteristics of that data and how it would be shared, and this agreement must be fair to both parties;
- If harmonised standards or common specifications have been published (which they have not yet), then the data should comply with these unless it can be shown to meet the essential requirements another way;
- Data and metadata must be suitable for sharing with the data user or, upon request from the user, a third party;
- Upon request from the user, the data holder must be ready to share the data with the user or a third party;
- A method should be established for calculating the reasonable level of compensation that can be claimed for transferring data to a third party or the authorities; and
- Before placing the product on the market, a machine builder outside the EU must appoint a legal representative who is established in the EU.

Other legislation

This article has covered the main EU legislation with which machine builders might need to comply. Depending on the nature of the machine, other directives could also apply. These range from the Low Voltage Directive (LVD, 2014/35/EU) and the Simple Pressure Vessels Directive (SPV, 2014/29/EU), to

the Pressure Equipment Directive (PED, 2014/68/EU) and ATEX Directive (2014/34/EU).

Digital Product Passports (DPP) are starting to be introduced for certain classes of products, such as batteries, motors and drives. Machine builders need to be aware of this issue and be ready to comply with relevant EU legislation when it comes into force.

Rules of origin

Aside from the technical aspects of CE marking, UK machine builders exporting to the EU must consider the complex rules of origin. This relates to customs declarations and is outside the scope of this present article. Nevertheless, it is essential that machine builders address this issue as well.

For information about appointing an EU authorised representative or legal representative, contact Hold Tech Files Ltd. www.holdtechfiles.eu