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Why you need to update your machinery CE marking paperwork

By Derek Coulson



With less than a year to go until the new EU Machinery Regulation supersedes the Machinery Directive, machine builders must ensure they are ready for the changes. And that includes manufacturers of series machines that are already in production, if those machines will be sold in the EU after 20th January 2027.

There is no transition period. Manufacturers of series machines need to be ready for what will, in effect, be an overnight change from the Machinery Directive 2006/42/EC to the Machinery Regulation 2023/1230. However, there are some new essential health and safety requirements (EHSRs) such as those relating to cybersecurity. Any component with a USB or network port will require an assessment. Any machinery linked to networks or internet, or autonomous operation will probably need competent assistance from IT professionals.

It is imperative that machine builders study the new Machinery Regulation and understand the implications. It might be necessary to undertake a new risk assessment for the whole machine or just relevant aspects of it. Depending on

the outcome of the risk assessment, changes to the design, software or hardware might be required.

Any machinery in Annex I (formerly Annex IV) that is built to a harmonised standard will need a Notified Body Type Approval, until such times as standards are rewritten and harmonised to the Machinery Regulation. It is likely to be a significant time, months or years until these are all updated.

Updating the paperwork

For series machines, there should be a set of instructions for use and an EU Declaration of Conformity, or assembly instructions and an EU Declaration of Incorporation for partly completed machines. In addition, the manufacturer should have paperwork relating to the quality assurance procedure, as well as the technical file or technical documentation.

For compliance with regulation 2019/1020 on market surveillance and compliance, it is likely that there is a mandate specifying the tasks to be performed by an Authorised Representative (EU AR).

All of these documents will need to be reviewed and revised when the CE marking on the machine relates to the new Machinery Regulation, rather than the current Machinery Directive.

Instructions

One change is that instructions for use no longer have to be provided in 'hard copy', as the Machinery Regulation allows these to be provided digitally. However, a hard copy must be provided free of charge if requested when the machine is ordered. Machine builders can potentially save money by not including a printed set of instructions with every machine, but they will need to establish a procedure by which printed instructions can be requested and supplied.

For partly completed machinery, the assembly instructions may likewise be provided digitally, with the person incorporating the partly completed machinery having the option to request a free printed copy.

Machine builders can now choose to provide an internet address or machine-readable code (eg QR code) from where the EU Declaration of Conformity can be accessed. If the instructions are being updated, this could be an opportunity to provide such access.

Declaration of Conformity

From 20th January 2027, the EU Declaration of Conformity (DoC) (previously an EC Declaration) must refer to the Machinery Regulation 2023/1230 instead of the Machinery Directive 2006/42/EC. Note that a number of minor revisions will

need to be made to the DoC, such as including the following statement: ‘This declaration of conformity is issued under the sole responsibility of the manufacturer.’

Within the Machinery Regulation, Annex V Part A states what the Declaration of Conformity must contain.

Previously, a machine might have been accompanied by more than one DoC relating to different Directives or Regulations. Under the new Machinery Regulation, however, it is permissible to draw up a single DoC that lists all of the laws with which conformity is being claimed.

For partly completed machinery, the changes to the DoI are similar to those for the DoC (see Annex V Part B).

Note that as many existing standards will not be harmonised to the Machinery Regulation, these should not be listed on Declarations.

Quality assurance paperwork

Text in the Machinery Regulation relating to quality assurance is substantially the same as in the Machinery Directive, though in places it has been redrafted and expanded for clarity. For machine builders, therefore, the only revisions to quality assurance paperwork are likely to stem from any changes necessary for complying with new EHSRs, such as those relating to cybersecurity.

Technical documentation

In the old Machinery Directive, the term ‘technical file’ was used when referring to machinery, whereas ‘technical documentation’ was used for partly completed machinery. In the new Machinery Regulation, ‘technical documentation’ is used for both.

Unfortunately, some areas of the new Machinery Regulation Annex IV (Technical documentation) are a little vague. For example, the Machinery Directive requires the technical file to include a ‘general description’ of the machinery, while the Machinery Regulation requires a ‘complete description’ – and there is no explanation of what ‘complete’ means.

Broadly speaking, the technical documentation must contain more detail than previously.

Authorised representative mandate

Today, under EU regulation 2019/1020 on market surveillance and compliance, machine builders are required to have an economic operator established in the EU. In line with the EU’s New Legislative Framework (NLF), the new Machinery Regulation requires the same.

Unless a UK machine builder has a related company based in the EU, it is likely that the only feasible way to name an economic operator in the EU is to appoint an EU Authorised Representative (EU AR). The machine builder must provide a mandate that specifies which tasks the EU AR is authorised to perform. If a mandate already exists for compliance with regulation 2019/1020, then it will need to be updated to refer to the new Machinery Regulation as well.

Conclusion

In less than a year's time, machine builders exporting to the EU will need to be ready for the new Machinery Regulation, even if the only changes necessary are to the paperwork. Remember that if machines and the accompanying paperwork are not compliant, they could be held at the border.

Hold Tech Files Ltd is established in the Republic of Ireland and can therefore act as an EU AR. Furthermore, its consultants can provide advice to help machine builders prepare for the new Machinery Regulation.

For more information, contact Hold Tech Files Ltd. www.holdtechfiles.eu

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Contact details for publication

Derek Coulson
Hold Tech Files Ltd
Dun Iseal House
Newtown
Gaulsmills
Ferrybank
Waterford
Ireland
X91 F638
www.holdtechfiles.eu
derek@holdtechfiles.eu

About the author

Derek Coulson is a compliance specialist with over 25 years of experience, primarily in machinery safety. He is a director of Hold Tech Files Ltd in the Republic of Ireland, as well as the founder of Safe Machine Ltd, a UK-based machinery safety consultancy that operates globally.

About Hold Tech Files Ltd

Hold Tech Files Ltd is a company based in the Republic of Ireland that holds Technical Documentation within the EU on behalf of manufacturing companies based outside the EU.