

What non-EU manufacturers of industrial products must do to comply with European Regulation 2019/1020



INTRODUCTION

If you are a manufacturer of industrial products and equipment based outside the European Union (EU) and you export CE marked goods to the EU, you need to be ready for the new European Regulation 2019/1020 on market surveillance and compliance of products.

This comes into force on 16 July 2021 and there are important implications for manufacturers and suppliers.



SCOPE

Annex I of Regulation 2019/1020 lists approximately 70 product Directives that are affected by the new requirements. These include:

- 2006/42/EC Machinery Directive
- 2014/30/EU Electromagnetic Compatibility (EMC) Directive
- 2014/35/EU Low Voltage Directive (LVD)
- 2014/29/EU Simple Pressure Vessels Directive (SPVD)
- 2014/68/EU Pressure Equipment Directive (PED)
- 94/9/EC ATEX Equipment

Although this white paper focuses on the needs of manufacturers in the industrial sector, its contents are equally applicable to the supply of goods complying with other directives listed in Regulation 2019/1020, such as personal protective equipment (PPE), toys and recreational craft.



What is Regulation 2019/1020

Regulation 2019/1020 concerns market surveillance

Regulation 2019/1020 aims to strengthen the requirements for market surveillance by EU Member States. From a manufacturer's perspective, the regulation introduces new requirements relating to an 'economic operator'. Without having one of these established in the EU, you are prohibited from placing goods on the market.

What is an 'economic operator'?

An economic operator is responsible for ensuring the conformity documentation is available, co-operating with market surveillance authorities and informing authorities if there are reasons to believe that a product presents a risk. The new requirements relating to an economic operator will impact many businesses based outside the EU. Now the UK has left the EU and a new UK-EU trade deal has been signed, UK machine builders are definitely affected. An economic operator can be any of these:

- the manufacturer of the goods,
- the importer (where the manufacturer is not established in the EU),
- an authorised representative, or
- a fulfilment service provider when none of the above are established in the EU.

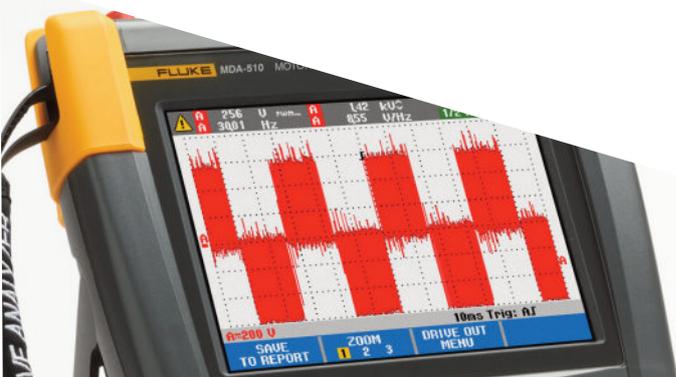
Article 3 of the Regulation provides definitions for these four terms.

A 'manufacturer' is any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark.

An 'importer' is any natural or legal person established within the Union who places a product from a third country on the Union market.

An 'authorised representative' is any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer's obligations under the relevant Union harmonisation legislation or under the requirements of this Regulation.

A 'fulfilment service provider' is any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the Council, parcel delivery services as defined in point 2 of Article 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council, and any other postal services or freight transport services.



What is changing

From 16 July 2021, Regulation 2019/1020 requires an Authorised Representative with a mandate to co-operate with the authorities if there is no other economic operator.

Non-EU manufacturers are likely to find that importers and fulfilment service providers are unwilling to accept the responsibilities associated with being an 'economic operator'. Furthermore, manufacturers may not wish to ask importers or distributors to hold their technical files because these contain valuable intellectual property. Consequently, the only other option available is to appoint an Authorised Representative.

With regard to the Machinery Directive, there is no change to the requirement for machine builders based outside the EU to have a person established in the EU to 'compile' the technical file. This remains the case for machinery and safety components supplied with a Declaration of Conformity (DoC), as well as partly completed machinery supplied with a Declaration of Incorporation (DoI). The person named on the DoC or DoI is responsible only for providing a technical file on reasoned request from authorities such as trading standards or health and safety authorities. See below for more information about authorisation to compile the technical file.

Appointing an Authorised Representative

For manufacturers that need an Authorised Representative (AR), Hold Tech Files Ltd offers a service by which it can act in this capacity for any of the Directives listed in Annex I of Regulation 2019/1020. This includes the Directives relating to industrial products and systems, and others ranging from aerosol dispensers, boilers and fertilisers, through to personal protective equipment (PPE), chemicals (REACH), cosmetics and weighing instruments.

Market surveillance and enforcement

To bolster market surveillance, the EU established a Union Product Compliance Network on 1 January 2021. This will 'serve as a platform for structured coordination and cooperation between enforcement authorities of the Member States and the Commission, and to streamline the practices of market surveillance within the Union, thereby making market surveillance more effective.'

The new Union Product Compliance Network makes it all the more important that machine builders meet the requirements relating to economic operators.

Authorisation to compile the technical file

In addition to the AR service, Hold Tech Files can also be named on the DoC or DoI as the person authorised to compile the technical file as required by the Machinery Directive. For this second service, Hold Tech Files has created a simple web-based portal where machine builders can sign a mandate, pay a fee and upload the relevant file to a secure server. Having paid the one-off fee, the manufacturer is entitled to name Hold Tech Files on the DoC or DoI for a period of up to Ten Years. This can be extended, the files modified or updated, and additional products added.





Brexit White paper

If you are a machine builder, you may well be interested in another white paper, 'The implications of Brexit for machine builders in the UK, the EU and the rest of the world'. Now the UK has left the EU and the two parties have agreed a new trading relationship, there are far-reaching implications for machine builders around the world. To learn more, download the free white paper from

www.holdtechfiles.eu



Hold Tech Files Ltd.

Hold Tech Files Ltd is established in the Republic of Ireland and can therefore be named as the Authorised Representative for compliance with European Regulation 2019/1020. This service will be of interest to manufacturers based outside the EU who do not have a subsidiary, distributor or agent willing to take on the responsibilities associated with this role. Contact Hold Tech Files for more information about the AR service.

In addition, Hold Tech Files can be named on the DoC or DoI as the person responsible for compiling the technical file. To this end, Hold Tech Files has created a web-based service for manufacturers of machines, partly completed machines and safety components covered by the European Machinery Directive. After signing a mandate and paying a fee, the customer can upload relevant files to a secure server. Payment of a one-off fee entitles the manufacturer to name Hold Tech Files on the DoC or DoI for a period of ten years.

Hold Tech Files Ltd,
Dun Iseal House,
Newtown, Gaulsmills,
Ferrybank, Waterford
Ireland, X91 F638.

www.holdtechfiles.eu | derek@holdtechfiles.eu



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COMPLIANCE Risk Software uses detailed checklists to simplify the risk assessment process. This software tool can be used by any competent machine designer, control system designer, safety professional, consultant or end user. It saves time during machine design and development, when preparing the technical file for CE marking and UKCA marking, and during CE/UKCA audits, PUWER Assessments and EN ISO 13849 Control Integrity Assessments. Visit the website to download a free trial of the software.

DD IT Solutions Ltd,
NETPark, Thomas Wright Way,
Sedgefield, Co Durham,
TS21 3FD, UK.

www.compliancerisksoftware.co.uk | info@ddits.co.uk

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Safe Machine Ltd.

Safe Machine Ltd was founded by Derek Coulson in 2012 to offer a range of machinery safety services. These include CE marking, CE audits, UKCA marking, UKCA audits, PUWER inspections and training. Derek Coulson is a machinery safety specialist with over 25 years' experience.

Safe Machine Ltd,
Belasis Business Centre, Coxwold Way,
Billingham, Tees Valley,
TS23 4EA, UK.

www.safemachine.co.uk | derek@safemachine.co.uk

safe:machine

About the author

Derek Coulson is a machinery safety specialist with over 25 years' experience. He is the founder of Safe Machine Ltd, a consultancy based in the UK, and a director of Hold Tech Files Ltd in the Republic of Ireland.



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The information contained in this white paper is intended as a guide only and is believed to be correct at the time of going to press. However, it remains the reader's responsibility to comply with all applicable regulations.

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Dun Iseal House, Newtown
Gaulsmills, Ferrybank
Waterford
Ireland
X91 F638

www.holdtechfiles.eu
derek@holdtechfiles.eu



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