
The European Union – What's in it for US Machinery Manufacturers?



What do US machinery manufacturers have to do to get into the EU market?

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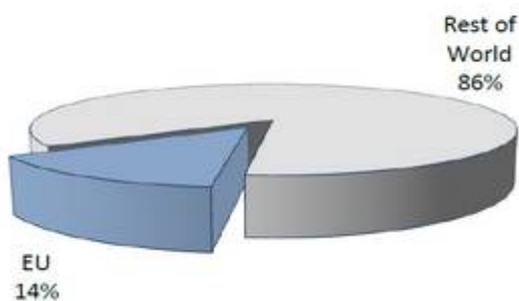
Preparing American made machinery to be exported to Europe can seem a daunting task, but with the expert advice and guidance, you too can gain access to the lucrative European market.

Robin J Carver describes how to ensure your machines will be Europe compliant.

The European Union – What’s in it for US Machinery Manufacturers?

Machinery manufacturing is one of the largest and most competitive sectors of the American manufacturing economy. In 2012, the United States exported \$23.6 billion worth of machinery to the European Union (the “EU”).

EU Share of US Machinery Exports, 2012



Source: US Census

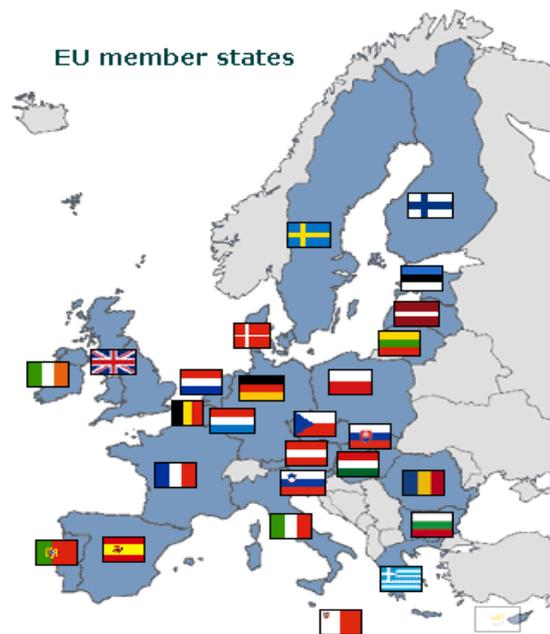
But with implementation of the Transatlantic Trade and Investment Partnership (TTIP) it is expected to increase annual US machinery exports to the European Union (EU) by \$10.0 billion, a rise of over 42% from 2012 levels!

Key to the European Union is economic integration. ALL the 28 Member States have harmonized their regulations. Thus for entry into, and trade within, the European markets, conformity with European Union Directives (*EU Laws*) is mandatory for a wide range of products, including machinery. In order to indicate that the requirements of the appropriate directives have been applied, machinery must be marked with the letters “CE” to indicate that the manufacturer has undertaken all assessment procedures required by these directives.

Which are the Member States of the European Union?

- | | |
|----------------|----------------|
| Austria | Italy |
| Belgium | Latvia |
| Bulgaria | Lithuania |
| Croatia | Luxembourg |
| Cyprus | Malta |
| Czech Republic | Netherlands |
| Denmark | Poland |
| Estonia | Portugal |
| Finland | Romania |
| France | Slovakia |
| Germany | Slovenia |
| Greece | Spain |
| Hungary | Sweden |
| Ireland | United Kingdom |

The European Economic Area (EEA) unites the EU Member States and the three EEA EFTA States (Iceland, Liechtenstein, and Norway) into an Internal Market governed by the same basic rules including CE Marking of machinery. Switzerland and Turkey are not EU or EEA members but have adopted common rules for trade including CE Marking of machinery.



What do US machinery manufacturers have to do to get into the EU market?

The European Commission describes the CE marking as the “*passport*” that allows manufacturers to trade industrial products freely within the internal market of the EU together with other aligned markets in Europe.



Testing and certification for the U.S. market are **NOT** sufficient for exporting to the EU. Manufacturers will need to start from scratch in order to determine what it takes to comply with EU requirements.

The upside is that since EU legislation harmonizes mandatory requirements for product safety throughout the European Union, a manufacturer only needs to go through the process once and can then export to ALL the 28 member states.

The CE mark is not a quality mark and does not indicate conformity to a particular standard; rather it indicates conformity to the legal requirements of the EU directives.

There are more than 20 directives setting out the product categories requiring CE marking. CE marking applies to products, ranging from electrical equipment to toys and from civil explosives to medical devices, however, not all products sold in the EU need to bear CE marking.

As manufacturer, supplying equipment covered by a “CE Marking” Directive (also known as a “New Approach Directive”) to the EU, it is your responsibility to:

- carry out a “conformity assessment”;
- compile the “Technical File”;
- draw-up a “EC Declaration of Conformity”;
- place the CE marking on the equipment.



For machinery, the following directives may have to be considered and applied:-

- **Machinery Directive (“MD”) - 2006/42/EC;**

For the machines electrical systems and associated electrical equipment:-

- **Low Voltage Directive (“LVD”)- 2014/35/EU;**

AND

- **Electromagnetic Compatibility (“EMC”) Directive - 2014/30/EU;**

For machines with medium/high capacity pressurised systems:-

- **Pressure Equipment Directive (“PED”) – 2014/68/EU**

An “overview” of the Directives for Machinery

The Machinery Directive - 2006/42/EC

The Machinery Directive (MD) sets out some 60 general “*Essential Requirements*” ranging from the need to reduce risks, defining “danger zones”, use of safe materials, requirements for control systems, characteristics of guards & protective devices, isolation of power, safe cleaning & maintenance, the provision of information and the placing of the CE Mark. It also gives essential requirements for special categories and types of machinery including certain agri-foodstuffs machinery, mobile machinery; requirements for lifting operations; etc.

Clearly, some machines pose a higher degree of risk and the Machinery Directive lists, high risk types of machinery and safety components for which more burdensome “special procedures” must be applied.

Under the Machinery Directive, the essential requirements are known as the “Essential Health & Safety Requirements” or the abbreviation, EHSR’s. Machinery that does not meet with the EHSR is unacceptable for placing “on the market” or for use in the European Union. Machinery which meets all the “Essential Health & Safety Requirements” of the Machinery Directive is acceptable and this is declared by the manufacturer (or authorised representative) in the EU by marking the machine with a CE Mark and issuing a formal written Declaration.

The CE Mark on your machine, supported by a formal written Declaration and the holding of the appropriate documentation, allows the machine to be placed legally “on the market” in the European Community.

Directives associated with the Machinery

Directive

The Machinery Directive, although the most significant directive for machinery compliance, is not necessarily a “stand alone” directive and other directives may have to be applied or referred to when CE Marking your machine.

For the machines electrical systems and associated electrical equipment:-

The Low Voltage Directive - 2014/35/EU;

The Low Voltage Directive (LVD) is to ensure that electrical equipment provides a high level of protection for the users in the European Union. The scope of the LVD covers machinery control panels, switch gear and electrical equipment intended for incorporation into machinery such as transformers and motors.

The Directive sets out eleven “safety objectives”, which represent the essential requirements of this Directive.

The Machinery Directive effectively incorporates the eleven “*Safety Objectives*” of the Low Voltage Directive into its “*Essential Requirements*” where the machinery includes electrical equipment.

AND

The Electromagnetic Compatibility (EMC) Directive - 2014/30/EU

The Electromagnetic Compatibility (EMC) Directive concerns both the electromagnetic emissions and immunity of electrical equipment, to ensure that, in use, the equipment does not disturb radio and telecommunication, as well as other equipment, and also determines the immunity of the equipment to interference, so that it is not disturbed by radio emissions normally present when used as intended.

The EMC Directive recognises two sorts of equipment “*Apparatus*” and “*Fixed Installations*”.

For machines with high capacity pressurised systems:-

The Pressure Equipment Directive – 2014/68/EU

The Pressure Equipment Directive provides regulation over pressure equipment with a pressure greater than 0.5 bar with specified volumes. Pressure equipment includes vessels, piping, safety accessories and pressure accessories and assemblies of pressure equipment.

Getting help, guidance and advice

The CE Marking process was designed to allow for “self-certification” by the manufacturer and/or the supplier into Europe. However, for those unfamiliar with the territory, the process can seem a confusing and time absorbing process. You will most likely need some guidance and advice.

The directives allow the formal appointment of organisations considered to be competent to make independent judgments about whether or not a product complies with the directives. These are called “Notified Bodies”. It is a common mistake to think that these “Notified Bodies” provide advice on or will do the CE Marking.

A “Notified Body” is specifically prohibited from offering advice and guidance and will NOT CE Mark your machinery!

Under their terms of their registration “Notified Bodies” must maintain impartiality and independence and can only indicate how and where a machine fails to conform but **they may NOT advise on any remedial actions!**

Robin J Carver has no such restrictions and offers a complete CE marking service with expert advice and guidance!

As an experienced Machine Builder, Control Systems designer and a Machine Safety Practitioner, Robin has established the highest degree of credibility as an expert in the field of European compliance for machinery in the UK and across Europe and is best positioned to help you get access into the European market.

How can Robin J Carver help you?

Put simply, Robin J Carver will ensure that your machine is in accordance with European Union Law allowing you to put your machinery into all or any of the Member States of the European Union, EFTA and the other “aligned” states.

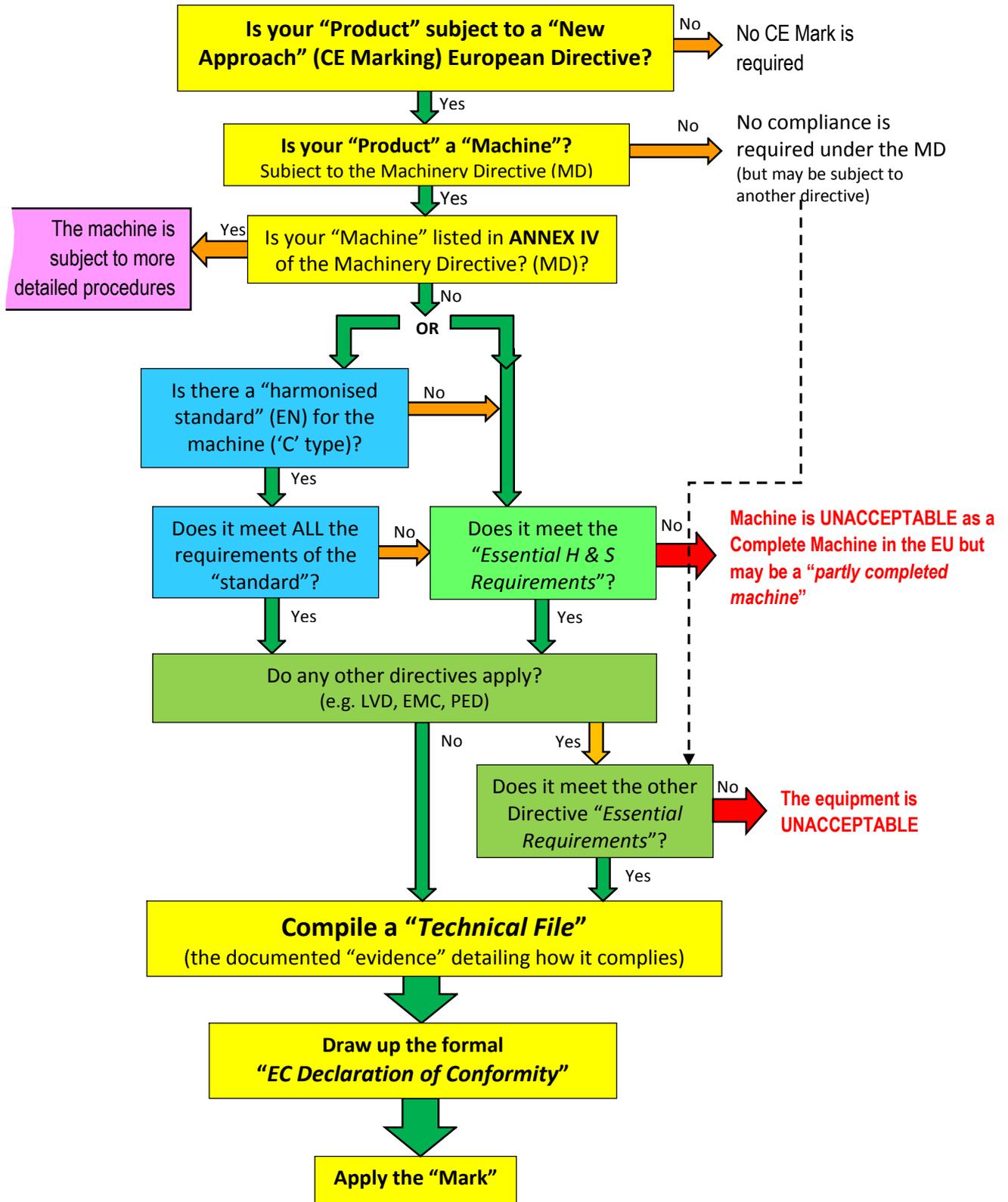
Services typically include:-

1. Identifying all applicable European Union (EU) Directives (The “Laws”);
2. Assess your machines’ alignment to the “*Essential Requirements*” contained in the directives (the legal requirements);
3. Determine any applicable standards that may be used or referenced – Harmonized European “*C type*” or “*B type*” standard(s) (EN’s), International (ISO, IEC, etc.) or alternative;
4. Perform verification and validations as required by the standards applied;
5. Choose the best and the most effective conformity assessment procedure; and if necessary, choose a “*Notified Body*” to perform any necessary “*EC type-examination*” procedure on the machinery or undertake a “*Full Quality Assurance*” procedure;
6. Assemble the required approvals and certificates;
7. Assist in the preparation of compliant User Manuals;
8. Assist in the preparation of the formal “*Technical File*”;
9. Prepare the “*EC Declaration of Conformity*” (a legally binding document);
10. Affix the “CE Marking” in full accordance with the EU Directive(s);
11. Assist you with the appointment of an authorized representative for your Company, or a “*Custodian of the Technical File*” (see below), in the EU;

Finally – provide follow-on support and advice when you need it. - Always readily available to provide ongoing or ad-hoc support.

What is the CE Marking process for a machine?

The process of CE Marking of machinery is best illustrated as a simplified logical process as below:-



What is the “Technical File”?

The “Technical File” must contain the information essential for verification of conformity with the Essential Requirements of the Directive(s). It is the “evidence” file for demonstration of compliance.

The “*Technical File*” must demonstrate to the appointed market surveillance authorities of any of the Member States in the EU that the machinery complies with the requirements of the Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for assessment.

A “*Technical File*” is required for each ‘model’ or ‘type’ of machine. It is possible for a ‘type’ of machinery to have variants; however, to be considered as belonging to the same ‘type’, variants must have the same basic design, present similar hazards and require similar protective measures. A ‘type’ of machine may be produced in series or as a single unit.

The “*Technical File*” must be made available to the “*Competent Authorities*” of the Member States for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced. The technical file does not have to be located in the EU, nor does it have to be permanently available in hardware form. However, it must be capable of being assembled and made available within a reasonable period of time by the person designated in the EC Declaration of Conformity (the Custodian).

The Machinery Directive requires that the manufacturer must always indicate, in the EC Declaration, the name and address of a **natural or legal person established in the EU** who is authorised to present the “*Technical File*” when it is demanded by the authorities.

Robin J Carver is a natural or legal person established in the EU and so, going forward, and having provided you with the primary support, above, then Robin would be pleased to act on your behalf as the declared custodian of the “*Technical File*”.

CONFIDENTIALITY

It is appreciated that the “*Technical File*” could contain commercially sensitive or confidential information. The “*Competent Authorities*” are bound to respect the confidentiality of all the information given to them. There is no obligation to communicate elements of the technical file to anybody other than the “*Competent Authorities*” of the Member States.

The manufacturer is under no obligation to reveal the content of the “*Technical File*” to his customers.

What is the “EC Declaration of Conformity”?

The “*EC Declaration of Conformity*” is the manufacturer’s statement that machinery is placed in the market in accordance with requirements of the Directive(s), in particular the essential requirements.

The Declaration also confirms that the manufacturer, or the appointed “*Custodian*” in the EU, can compile the “*Technical File*” providing the evidence, to the regulating authorities, of how conformity has been achieved.

			
EC Declaration of Conformity with the European Machinery Directive 2006/42/EC			
We hereby certify that the machine detailed below complies with all relevant provisions of the EC Machinery Directive 2006/42/EC and National Laws and Regulations adopting this Directive.			
Declaration Ref. No.:-	DC12345		
Manufacturer:-	Long Widget Mfg. Inc.		
Manufactures Address:-	513 Wilson Rd, Oldsville, LA 71234, United States		
Name of the person authorised to compile the technical file (in EU):-	Robin J Carver RSP		
Address of the person authorised to compile the technical file (in EU):-	71 Empire Square, Long Lane, London, SE1 4NB, United Kingdom		
Product:-	Right Angle Widget Finishing Machine		
Description:-	Fixed Installation machine for final assembly and finishing of Right Angle Widgets		
Serial No.:-	WFM 12345		
We hereby declare that the machine detailed also complies with all relevant provisions of the following other EC Directives:-	Pressure Equipment Directive 97/23/EC		
Harmonised Standards Applied (in full):-	EN 693:2001+A2:2011 - Machine tools - Safety - Hydraulic presses		
Harmonised Standards referenced (partial application):-	EN ISO 12100; EN 60204-1; EN ISO 13849-1; EN 953 & EN 1088		
Person empowered to draw up the declaration:-	Dr. V Clever	Signature:-	<i>Vic Clever</i>
Position:-	CEO - Long Widget Mfg. Inc.		
Place of issue:-	513 Wilson Rd, Oldsville, LA 71234, United States	Date:-	30 February 2013

What are the consequences of not acquiring the CE Marking?

US Exporters have discovered that no matter how interested European companies are in their machinery they will not take the risk of buying non-compliant products.



European companies too have obligations under the Use of Work Equipment Directive to only purchase correctly CE Marked equipment. They will not risk the large financial penalties and potential prosecutions that the EU makes possible by making the users in the EU responsible for the equipment they purchase.

In addition, under the provision of the “New Legislative Framework Directive”, the EU Customs Authorities have the powers to, seize, hold, return or even destroy non-compliant imports!

“Member States shall lay down the rules on penalties applicable to infringements and shall take all measures necessary to ensure that they are implemented.”

“The penalties provided for must be effective, proportionate and dissuasive.”

(Machinery Directive – Article 23 “PENALTIES”)

