

CE Program

Notified Body Services For Machinery

Directive 98/37/EC



Machinery Compliance

The European Parliament has adopted Machinery Directive (98/37/EC) to ensure that machinery which is placed into service within the European Community satisfies the *essential health and safety requirements* (EHSR) as defined by the Directive. This implementation of conformity assessment procedures is expected to reduce the social cost of accidents caused by the use of machinery.

SAI Global is an approved European Notified Body to provide CE Marking conformity assessment services for machinery, including those listed in Annex IV, such as saws, moulding machines, presses, woodworking machinery and vehicles servicing lifts.

SAI Global has been certifying products for over 40 years in over 50 countries. Let SAI Global look after your compliance and assurance requirements in a simple and straight forward manner.

Overview of Machinery Directive

Machinery is defined as an assembly of linked components at *least one which moves*, with the appropriate actuators, control and power circuits, joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material.

The directive defines the *general* and then the *specific* health and safety requirements in accordance with the hazards which they cover. Each of the groups below has defined requirements.

1. General
2. Specific: Certain categories of machinery –
 - Agri-foodstuffs machinery e.g. cooking, refrigeration, thawing, washing, handling, packaging, storage, transport or distribution
 - Portable hand-held and/or hand-guided machinery
 - For working wood and analogous materials
3. Mobile machinery: self-propelled, towed or pushed or carried by other machinery or tractors

4. Lifting machinery
5. For underground work
6. Lifting or moving persons

Some general essential requirements are

- Adequate lighting shall be provided
- Normal/emergency stopping shall be clearly identifiable, visible
- Interactive software between operator and machine shall be user friendly
- Stability against overturning, falling, break up
- Prevention of risks related to moving parts

What is CE Marking?

CE Marking is a mark affixed to a product by the manufacturer to demonstrate that the product complies with all applicable European New Approach Directives.



CE Marking indicates to officials that the product may be legally offered for sale in any country within the European Economic Area.

Steps for Machinery CE Marking

Option 1

Products that do not fall under Annex IV require the development of a Risk Assessment and a Technical File (Annex V) including manufacturer's Declaration of Conformity (Annex IIA). SAI Global can provide a review / gap-analysis of your information.

Option 2

Products that fall under Annex IV, which do not fully comply with harmonised, an EC Type Examination is required by a Notified Body. This is in addition to the development of a Risk Assessment and a Technical File and manufacturer's Declaration of Conformity. SAI Global can issue the EC Type Examination Certificate and verify your information.

Option 3

Products that fall under Annex IV, which fully comply with harmonised norms, the manufacturer can choose to

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- Submit the product to EU Notified Body for EC-type examination. Process as in Option 2 would apply.
- Submit information (including Risk Assessment and Technical File) to a Notified Body for their verification. Notified Body will issue a Certificate of Adequacy. Manufacturer completes a Declaration of Conformity.

SAI Global offers both of these services as Notified Body.

Once the manufacturer is satisfied that they have met the compliance requirements, they can sign the Declaration of Conformity and affix CE Mark on the product in accordance with the Directive(s).

Requirements for the Technical File

The Technical File must include

- An overall drawing of the machinery and schematics of the control circuits
- Full detailed drawings, design calculations, functional test data, etc., for conformity verification with the EHSR
- A list of the EHSRs
- A Declaration of Conformity referencing the relevant standards, signed by the manufacturer.
- A Risk Assessment.
- Notified Body issued Certificates as applicable)
- Technical reports
- Operating and maintenance manuals (written in language(s) used in the countries the machinery is to be used)
- For series manufacturers, the internal measures that will be implemented to ensure that the machinery remains in conformity with this directive.

Overview of SAI Global and Product Certification

SAI Global has been assessing products and systems for over 40 years, initially as part of a national Standards Body, and since 2003, as a publicly listed assurance provider.

SAI Global Product Certification services provide third party assurance that a particular product fulfils the specified requirements of a nominated Directive(s)/Product Standard(s). For the end users it provides a high degree of confidence that the product will perform according to the specified standard.

SAI Global Product Certification:

- Issues over 3000 product certificates
- Certifies clients in over 50 countries
- Certifies in over 500 ISO, EN, Australian and other standards
- Has more than 40 years of product certification expertise

SAI Global issues a number of approval marks, such as:



Inform...Train...Assess

Whether you need to satisfy contractual agreements, demonstrate regulatory compliance, improve internal processes, or enhance your competitive edge, SAI Global can help. To learn more about our CE Marking Services, to determine whether you need an assessment by an approved European Notified Body, or to purchase standards including European Norms, please visit us at www.saiglobal.com/assurance.

Let SAI Global look after your assurance needs.

We welcome your contact via

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