

Modulo Uno

Machinery Directive

2006/42/EC Directive



The Machinery Directive

The 98/37/EC Directive, that has replaced the 89/392/EEC one and the following reviews, has been replaced from December 29th 2010 by the new 2006/42/EC Machinery Directive.

The Scope

The new 2006/42/EC Machinery Directive has redefined the scope of the previous Directive replaced, by listing explicitly a whole series of categories of machinery to which the Directive must be applied. Moreover, some exclusions have been redefined/clarified and new categories of products have been added.

The Machinery Directive (MD) requires manufactures of: machinery, interchangeable equipments, safety components (ANNEX V), lifting accessories, chains, ropes and webbing and

removable mechanical transmission devices, to affix the CE mark and to draw up the CE declaration of conformity, in order to state the compliance with the Essential Safety and Health Requirements (ESHR's) of which to the Annex I.

Machinery can be described as "an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application" ... omississ....

The Machinery Directive is also applied to "partly completed machinery", that has been defined as "an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies" ... omississ...

Technical file

The manufacture has to compile for every product that reverts within application of the MD a technical file (ANNEX VII) that he has to show the conformity of the product to the ESHR's (ANNEX I). The technical file has to contain the necessary documentation to testify the correct criterions of design, manufacture and operation in relationship to the safety aspects.

Certificative schemes

Any machinery, in order to bring the CE mark, has to be comply with the ESHR's set out in the ANNEX I of the Machinery Directive itself. The MD distinguishes between two types of machine: a group, specified

within the ANNEX IV, which includes the machinery considered more dangerous and another group for all the other machines.

The manufacturer has to verify the belonging of the owned product to the ANNEX IV and then choose the certification scheme, among the admitted procedures, according to the standards harmonized to guarantee the compliance with the ESHR's (ANNEX I).

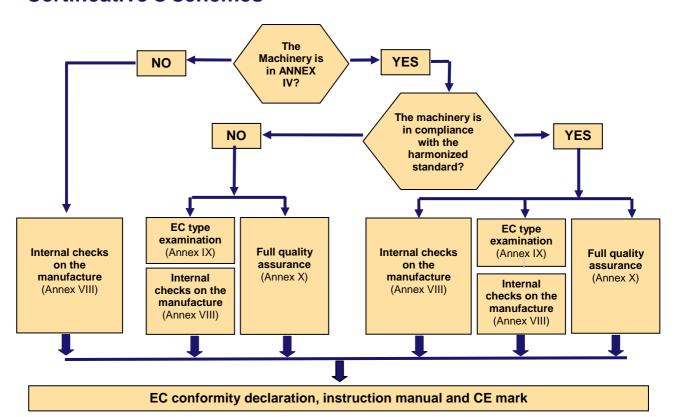
Among the certification schemes, only the ANNEX IX and X procedures require the intervention of a Notified Body.

The function of the Notified Body concerns the following:

- ANNEX IX (module B Type Examination): the Notified Body analyses and evaluates the documentation, verifies that the prototype has been manufactured according to the technical documentation; performs directly or indirectly the required tests.
- ANNEX X (module H Full Quality Assurance): the Notified Body audit the Quality System of the manufacturer in order to verify the compliance with the ESHR's (ANNEX I and X).
- For machinery not included in the ANNEX IV, the intervention of a Notified Body is not required.

A machinery manufacturer is always allowed to submit voluntary the machinery to a Notified Body for obtaining a certificate of approval: checks of third part.

Certificative's schemes



Eurofins-Modulo Uno SpA is Notified Body for the Machinery Directive: we have a team of highly qualified technical experts in charge of developing and providing activities in the certification field and, in particular, for the CE certification in compliance with EU directives.