



CERTRUST LTD.
2006/42/EC Directive
MACHINERY



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MACHINERY DIRECTIVE

Machinery must be subject to conformity assessment procedure at the design and production stages before it can be placed on the EU market or put into service. Conformity assessment procedure is also the responsibility of the manufacturer in case the design or production of the product is subcontracted.

The applicable conformity assessment procedure is determined by the legislation correspondent to the equipment. These are typically the responsibility of the manufacturer, but in some cases it is necessary to involve a notified body in order to carry out certain tasks.

There are eight conformity assessment modules (modules A to H according to Decision 768/2008/EC), which prescribe the responsibilities of the manufacturer and the need to involve the Notified Body to carry out certain tasks.

The Directive (2006/42/EC) applies to the following products: machinery, adaptable equipment, safety components, load carrying devices, chains, ropes and belts, Detachable drive lines and partly completed machinery.

Other types of machinery that are excluded from the scope of the Directive: Machinery used at trade fairs, in the nuclear industry, in laboratories and mines, or in machinery used by the military or the police.

TASKS CARRIED OUT BY THE NOTIFIED BODY CAN TYPICALLY BE DIVIDED INTO THREE GROUPS:

technical tests of the product

examination of technical documentation

inspection of the manufacturer's quality system (audit)

ACCORDING TO DIRECTIVE 2006/42/EC:

Module A - Implementation and operation of an internal production control system

Module B - EC type-examination by a Notified body

Module H - Full quality assurance, which covers the implementation and operation of a quality management system which is certified by a Notified body.

WHAT DOES EACH MODULE MEAN?

MODULE A - INTERNAL PRODUCTION CONTROL:

The manufacturer or his authorized representative established within the Community shall ensure that the equipment in question satisfies the requirements of the Directive which apply to it.

MODULE B - EC TYPE-EXAMINATION:

The notified body shall verify and certify that the product, which is in accordance of the production envisaged, meets the essential requirements of the Directive which apply to it.

MODULE H - QUALITY MANAGEMENT SYSTEM VERIFICATION:

The manufacturer must operate an approved quality system for production, final product inspection and testing. One model of this quality system is the ISO 9001 quality management system and similarly to demonstrate the adequacy and operation of the system through periodic audits.

Which module you need to use for a particular machine, or which modules you can choose from, is depending on:

Whether the machinery is covered by Annex IV of Directive 2006/42/EC?

Whether harmonized standards exist for the equipment and have been applied during design/ production.

If the machine is on the list referred to above and there is no harmonized standard that applies to it, or it has not been (or not fully) applied, the involvement of a Notified Body is mandatory during the CE marking process!

In the case of „Module A“, there is no obligation to involve a Notified Body, all tasks can be performed independently by the manufacturer.

