

Modulo Uno

Pressure Equipment

The 97/23/EC European Directive



European Directive 97/23/EC

The CE Marking affixed on pressure equipment refers to the enforcement of the 97/23/EC European Directive, also known as PED.

The coming into force of the Directive is effective from May 29th, 2002.

The Directive sets criteria for design, manufacturing and testing of pressure equipment and, in general, of systems for which the Maximum Allowable Pressure (PS) is greater than 0,5 bar, and for the conformity assessment procedures to be applied to an item of pressure equipment in order to affixing on it the CE Marking.

The Directive lays down essential safety requirements which the manufacturer has to be compliant with, both for equipment and production process: indeed, the manufacturer has to assess and reduce any risk related to the pressure equipment sold on the market and put into service.

The enforcement of the 97/23/EC European Directive guarantees the free circulation in safety of pressure equipment on the European market.

Marking and Certification

The manufacturer applies the Certification Module according to the Category of the equipment, which depends on the fluid for which it is intended to be used, on the Maximum Allowable Pressure (PS) and on its volume (V) or Nominal Size (DN). Once defined the Category, the Directive defines the Certification Modules applicable to the equipment.

Finally, the manufacturer chooses the specific Certification Module according to the production process (one-off or mass production), to the presence or not of a company Quality Assurance System and to the Category of the equipment.

For equipment of Category I, the manufacturer is solely responsible for the certification process. For equipment of Category II, III and IV, the manufacturer shall apply to a Notified Body, whose activity will depend on the Certification Module and may consist of type-examination, assessment on the company quality system and periodical auditing, assessment on the production process and on the final product, assessment on the qualifications of the personnel undertaking the non-destructive tests and, more in general, all the final inspections and proof tests referred to verify the conformity to the safety requirements set by the Directive.

After the successful completion of the assessment procedures and before selling the equipment, the manufacturer must affix the CE Marking to each item and, if

involved, affix the identification number of the Notified Body responsible for surveillance. Then, the manufacturer must draw up a Declaration of Conformity. The affixing of the CE Marking certifies the compliance with the 97/23/EC Directive and with all other Directives enforceable.

CATEGORY — I	MODULE A - Internal Production Control One-off or mass production without an approved QAS.		The manufacturer ensures and declares the compliance.	
CATEGORY —	MODULE A1 - Internal manufacturing checks with monitoring of the final assessment One-off or mass production without an approved QAS.		The manufacturer ensures and declares the compliance. The Notified Body monitors the final assessment performed by the manufacturer.	
-	MODULE D1 - Production Quality Assurance One-off or mass production with an approved QAS for production, final inspection and testing.		Conformity of production, inspection and testing. The Notified Body assesses the Quality System.	
L	MODULE E1 - Product Quality Assurance One-off or mass production without an approved QAS.		Conformity of final inspection and testing. The Notified Body assesses the Quality System.	
CATEGORY — III	MODULE B - EC type- examination A Notified Body ascertains and attests that a representative example of the production meets the provisions of the Directive.	Module E - Product Quality Assurance Approved QAS for production, final inspection and testing.		The manufacturer declares the conformity with the type as described in the EC type examination certificate. The Notified Body assesses the QAS.
		Module C1 - Conformity to type Production process without an approved QAS.		Final assessment must be subject to monitoring in the form of unexpected visits by a Notified Body.
	MODULE B1 - EC Design- examination A Notified Body ascertains and attests that the design of an item of pressure equipment meets the provisions of the Directive.	Module D - Production Quality Assurance Mass production with an approved QAS for production, final inspection and testing.		The manufacturer declares the conformity with the type described in the EC design-examination certificate. The Notified Body assesses the QAS.
		Module F - Product Verification Production without an approved QAS.		The manufacturer declares the conformity with the type described in the EC design-examination certificate. The Notified Body performs the appropriate examinations and tests.
Ĺ	Module H - Full Quality Assurance Approved QAS, manufacture, final inspection and testing.		The manufacturer ensures and declares the conformity. The Notified Body assesses the Quality System.	
CATEGORY VI	MODULE B EC Type-examination A Notified Body ascertains and attests that a representative example of the production in question meets the provisions of the Directive.	Module D - Production Assurance Mass production with an a QAS for production, final i and testing.	with the type described in the EC type- pproved examination certificate.	
		Production without an approved QAS.		The manufacturer declares the conformity with the type described in the EC type-examination certificate. The Notified Body performs the appropriate examinations and tests.
	Module G - EC Unit verification One-off production without an approved QAS.		The Notified Body must examine the design and construction of each item of pressure equipment.	
	Module H1- Full Quality Assurance with design examination and surveillance of the final assessment Approved QAS for design, manufacture, final inspection and testing.		The manufacturer ensures and declares the conformity. The Notified Body issue an EC design-examination certificate, assesses the QAS, monitors the final assessment in the form of unexpected visits.	