

# 压力设备

欧盟指令 97/23/EC



## 压力设备指令

根据欧盟指令 97/23/EC (也被称为 PED 指令), 压力设备需标注 CE 标志, 自 **2002 年 5 月 25 日** 起在欧盟强制执行。

PED 指令针对最大允许压力大于 **0.5 帕斯卡** 的压力设备及系统, 为其指定从设计、制造到测试和认证的相关标准。

PED 指令还规定了压力设备在生产过程中的基本安全要求。



## 标识和认证

制造商需要根据设备分类来分别申请认证, 压力设备主要按照以下方面进行分类:

- ✧ 流体的用途
- ✧ 可允许的最大压力
- ✧ 产品的体积或容积

制造商选择其相应的认证模块后, 根据设备类别不同、质量保证系统不同进行一次性或批量生产。

**I 类 Category I**, 制造商需对认证过程全权负责。

**II 类, III 类和 IV 类**, 制造商需向公告机构申请认证。认证步骤详见下页。

评估过程顺利完成后, 制造商在产品上标注 CE 标志, 提交符合性声明, 产品即可推向市场。

**Eurofins 欧陆集团** 设立在意大利 Modulo 的实验室为压力设备的公告机构, 公告号 2049。我们为您提供压力设备的全面符合性评估、认证、培训、验货及咨询等服务。

**Eurofins 欧陆集团** 是国际著名的检测认证机构, 在食品、药品、环境和 **工业**、消费品等领域享有盛誉。欧陆集团在全球拥有 170 多个实验室, 遍布欧洲、美洲、亚洲、非洲 35 个国家, 拥有超过 13,000 名优秀员工。

**I 类**

<b>模块 A</b> <b>内部制程控制</b> 没有经过质量保证系统审核的制程	制造商声明其产品符合性
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**II 类**

<b>模块 A1</b> <b>内部制程控制 + 最终评估监测</b> 没有经过质量保证系统审核的制程	制造商声明其产品符合性。 由公告组织监视由制造商进行的最终评估。
<b>模块 D1</b> <b>生产质量评估</b> 经质量保证系统审核的批量生产并制程终检和测试。	制程、检验及测试的符合性。 由公告组织评估质量系统。
<b>模块 E1</b> <b>生产质量保证</b> 经质量保证系统审核的批量生产并产品终检和测试。	终检和测试的符合性。 由公告组织评估质量系统。

**III 类**

<b>模块 B</b> <b>EC 型式检验</b> 公告组织评估生产样本符合指令规定	<b>模块 E</b> <b>产品质量保证</b> 经质量保证系统审核的批量生产并产品终检和测试	制造商声明其产品符合型式检验证书中的样本。 由公告组织评估质量系统。
	<b>模块 C1</b> <b>型式符合</b> 没有经过质量保证系统审核的制程	最终评估必须受到公告组织以意外访问形式的监测
<b>模块 B1</b> <b>EC 设计审核</b> 公告机构评估压力设备的设计符合指令规定	<b>模块 D</b> <b>生产质量保证</b> 经质量保证系统审核的批量生产并制程终检和测试。	制造商声明其产品符合型式检验证书中的样本。 由公告组织评估质量系统。
	<b>模块 F</b> <b>产品验证</b> 没有经过质量保证系统审核的制程	制造商声明其产品符合型式检验证书中的样本。 公告机构对所有项目执行适当检查和测试。
<b>模块 H</b> <b>全面质量保证</b> 经质量系统审核的制程、终检和测试		制造商确保并声明其产品符合性。 由公告组织评估质量系统。

**IV 类**

<b>模块 B</b> <b>EC 型式检验</b> 公告组织评估生产样本符合指令规定	<b>模块 D</b> <b>生产质量保证</b> 经质量保证系统审核的批量生产并终检和测试。	制造商声明其产品符合型式检验证书中的样本。 由公告组织评估质量系统。
	<b>模块 F</b> <b>产品验证</b> 没有经过质量保证系统审核的制程	制造商声明其产品符合型式检验证书中的样本。 公告机构对所有项目执行适当检查和测试。
<b>模块 G</b> <b>EC 单元验证</b> 没有经过质量保证系统审核的一次生产		公告组织需检验每个压力设备的设计和结构。
<b>模块 H1</b> <b>涵盖设计审查和监督最终评估的全面质量保证</b> 经质量体系审核的设计、制程、终检和测试		制造商确保并声明其产品符合性。 公告组织出具EC设计审查证书，评估质量系统并以意外访问形式的对最终评估进行监测。

# Pressure Equipment

The 97/23/EC European Directive



## The Directive

The CE Marking affixed on pressure equipment refers to the enforcement of the 97/23/EC European Directive, also known as PED, mandatory **since May the 29<sup>th</sup>, 2002** for the free circulation of products on the European Market.

The Directive sets criteria for design, manufacturing, testing and certification of pressure equipment and of systems for which the Maximum Allowable Pressure (PS) is greater than 0,5 bar.

The Directive lays down essential safety requirements both for equipment and production process.

## 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,
- the Maximum Allowable Pressure (PS)
- the volume (V) or Nominal Size (DN) of the item.

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.

**Category I**, the manufacturer is *solely responsible* for the certification process.

**Category II, III and IV**, the manufacturer shall apply to a *Notified Body*.

The certification path may consist of several possible ways of assessment, as displayed in the following page.

After the successful completion of the assessment procedures, the manufacturer affixes the CE Mark, signs a Declaration of Conformity and can then put the products into the market.

Eurofins is an Notified Body (Eurofins – Modulo Uno, n. 2049) accredited to provide all necessary Conformity assessment and PED Certificates.

CATEGORY I	<b>MODULE A - Internal Production Control</b> One-off or mass production without an approved QAS.	The manufacturer ensures and declares the compliance.
CATEGORY II	<b>MODULE A1 - Internal manufact.checks with monitoring of the final assessment</b> One-off or mass production without an approved QAS.	The manufacturer ensures and declares the compliance. The NB monitors the final assessment performed by the manufacturer.
	<b>MODULE D1 - Production Quality Ass.</b> Mass production with an approved QAS for production final inspection and testing.	Conformity of production, inspection and testing. The NB assesses the Quality System.
	<b>MODULE E1 - Product Quality Assurance</b> Mass production with an approved QAS for product final inspection and testing.	Conformity of final inspection and testing. The Notified Body assesses the Quality System.
CATEGORY III	<b>MODULE B</b> <b>EC type-examination</b> A Notified Body assesses that a representative sample of the production meets the provisions of the Directive.	<b>MODULE E</b> <b>Product Quality Assurance</b> Mass production with an approved QAS for product final inspection and testing. The manufacturer declares the conformity to the type as described in the EC type examination certificate. The Notified Body assesses the QAS.
	<b>MODULE B1</b> <b>EC Design-examination</b> A Notified Body assesses that the design of a pressure equipment item meets the provisions of the Directive.	<b>MODULE C1</b> <b>Conformity to type</b> Production process without an approved QAS. Final assessment must be subject to monitoring in the form of unexpected visits by a NB.
		<b>MODULE D</b> <b>Production Quality Assurance</b> Mass production with an approved QAS for production final inspection and testing. The manufacturer declares the conformity to the type described in the EC design-examination certificate. The Notified Body assesses the QAS.
		<b>MODULE F</b> <b>Product Verification</b> Production without an approved QAS. The manufacturer declares the conformity to the type described in the EC design-examination certificate. The Notified Body performs the appropriate examinations and tests on all the items.
	<b>Module H - Full Quality Assurance</b> Approved QAS, manufacture, final inspection and testing.	The manufacturer ensures and declares the conformity. The NB assesses the Quality System.
CATEGORY VI	<b>MODULE B</b> <b>EC Type-examination</b> A Notified Body assesses that a representative sample of the production meets the provisions of the Directive.	<b>Module D - Production Quality Assurance</b> Mass prod. with an approved QAS, final inspec.and testing. The manufacturer declares the conformity to the type described in the EC design-examination certificate. The Notified Body assesses the QAS.
		<b>Module F - Product Verification</b> Production without an approved QAS. The manufacturer declares the conformity to the type described in the EC design-examination certificate. The Notified Body performs the appropriate examinations and tests on all the items.
	<b>Module G - EC Unit verification</b> One-off production without an approved QAS.	The Notified Body must examine the design and construction of each item of pressure equipment.
	<b>Module H1- Full Quality Assurance with design examination and surveillance of the final assessment</b> Approved QAS for design, manufacture, final inspection and testing.	The manufacturer ensures and declares the conformity. The Notified Body issues an EC design-examination certificate, assesses the QAS, monitors the final assessment in the form of unexpected visits.