TECHNICAL ARTICLE

CORTEM GROUP
To be sure to be safe.

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THE MODULAR APPROACH TO CERTIFICATION ACCORDING TO DIRECTIVE 93/465/EEC

We never had occasion in this newsletter to speak about the Modular Approach of Directive 93/465/EEC concerning the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, to be applied in the technical harmonization directives.

This directive, issued in 1993 but still valid today, defines both the basic rules regarding the marking of CE products, both the basic rules concerning the procedures for assessing the conformity of a product.

The table below shows the various modules which are provided by the Directive for the verification of the compliance of a product.

A	**Internal production control**	It is relevant to the internal manufacturing design and control. This module does not require the intervention of a notified body.
B	**EC-type examination**	It covers the design phase and must be followed by a report including the evaluation in the production phase. The EC-type examination certificate is issued by a notified body.
C	**Conformity to type**	It covers the production phase and follows the module B. It provides the conformity with the type described in the EC-type examination certificate issued according to module B. This module does not require the intervention of a notified body.
D	**Production quality assurance**	It is relevant to the production phase and follows the module B. It derives from the ISO 9000 quality assurance standard with the intervention of a notified body which has to approve and control the quality system established by the manufacturer for the production, the final product inspection and the testing.
E	**Product quality assurance**	It is relevant to the production phase and follows the module B. It derives from the ISO 9000 quality assurance standard with the intervention of a notified body which has to approve and control the quality system established by the manufacturer for the final product inspection and the testing.
F	**Test on the Product**	It is relevant to the production phase and follows the module B. A notified body examines the conformity with the type described in the EC-type examination certificate issued according to module B and issues a certificate of conformity.

G	**Test on a single product**	It covers the stages of design and manufacture. Every single product is examined by a notified body which issues a certificate of conformity.
H	**Full quality assurance**	It covers the stages of design and manufacture. It derives from the EN ISO 9001 quality assurance standard, with the intervention of a notified body that has to approve and control the quality system established by the manufacturer for the design, manufacture, final product inspection and testing.

The EC-type examination in accordance with the ATEX directive 94/9/EC

In the case of equipment subject to ATEX Directive 94/9/EC, i.e. for all equipment that are installed in hazardous areas for the presence of potentially explosive atmosphere, the EC-type examination is necessary for the following reasons:

• it verifies that the requirements of safety and health imposed by the Directive, even with tests that are performed only once in the product life;

• it checks the fulfillment of the Essential Safety Requirements, also through standards recognized by the Directive which lay the state of the art;

• because design errors must be corrected before the placing on the market of any product.

The EC-type examination is performed by a Notified Body, which, first, assess the project through the examination of the technical documentation in order to evaluate the compliance with the Essential Health and Safety Requirements of the Directive.

As a result, the examination is conducted on the prototype, through a series of tests, established by the laws in force, mentioned in the Directive. After an audit of perfect compliance with the relevant characteristics reported in the technical documentation, the certificate is issued.

Unlike the provisions of the previous rules, the EC-type examination is necessary but not sufficient to place the products on the market. The manufacturer has to demonstrate the control over production and a quality system certified according to ISO 9001 and ISO IEC 80079-34 standards. These certificates should be issued by accredited bodies.

Notified Bodies

The EC-type examination is performed by a notified body which must be unrelated to the manufacturer.

The notified body and the staff responsible for the EC type-examination must:

• carry out the tests with the highest professional integrity;

• have the technical competence including a satisfactory knowledge of the tests requirements, along with an adequate experience of the same and, also, the ability to draw up certificates, records and reports of the tests performed;

• be free from all pressures, particularly financial, which might influence the outcome of the inspection. The salary of each employee, especially, should not be commensurate to the number of tests carried out or on the results of the audits themselves.

Have a look at the list of notified bodies at the following link of the European Community:

http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=14