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Safety Certification of Consumer Products in Europe

Dipl.-Ing. Markus Weber
DIN CERTCO, Gesellschaft für Konformitätsbewertung mbH (Germany)

Introduction

For the certification of consumer products different systems in Europe exist. Most important is the mandatory certification system for products that have to meet basic requirements according to EU directives (CE-Mark). On the national level voluntary certification schemes which are based on the requirements that are laid down in national standards have been operational for a long time. One example for systems of this type are certifications for the German DIN-Geprüft (DIN Tested) mark. A new voluntary system is now developed by the European Committee for Standardisation (CEN). Products that meet the requirements that are laid down in European standards may bear the Keymark. The differences and similarities between these certification systems will be described briefly in the following chapters.

CE-Mark

Detailed information on the new approach of the European Commission and the CE-Mark can be found in the "Guide to the implementation of directives based on the New Approach and the Global Approach" which is available from the European Commission.

CE

Directives based on the New Approach of the European Commission

Products legally manufactured or marketed in one country of the European Union should in principle move freely throughout the community, if such products meet equivalent levels of protection. To achieve this aim a new regulatory technique and strategy was laid down by the Council Resolution of 1985 on the New Approach to technical harmonisation and standardisation, which established the following principles:

- Legislative harmonisation is limited to essential requirements that products placed on the Community market must meet, if they are to benefit from free movement within the Community.
- The technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonised European standards.

- Application of harmonised European standards or other standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements.
- Products manufactured in compliance with harmonised European standards benefit from a presumption of conformity with the corresponding essential requirements

Essential requirements are set out in the annexes to the directives. Products may be placed on the market and put into service only if they are in compliance with the essential requirements.

Table 1 New Approach directives (directives providing for the CE marking)

Directive	**Number of Directive**
Low voltage equipment	73/23/EEC 93/68/EEC
Simple pressure vessels	87/404/EEC 90/488/EEC 93/68/EEC
Toys	88/378/EEC 93/68/EEC
Construction products	89/106/EEC 93/68/EEC
Electromagnetic compatibility	89/336/EEC 92/31/EEC 93/68/EEC (98/13/EC)
Machinery	98/37/EC 98/79/EC
Personal protective equipment	89/686/EEC 93/68/EEC 93/95/EEC 96/58/EC
Non-automatic weighing instruments	90/384/EEC 93/68/EEC
Active implantable medical devices	90/385/EEC 93/42/EEC 93/68/EEC
Gas appliances	90/396/EEC 93/68/EEC
Hot water boilers	92/42/EEC 93/68/EEC
Civil explosives	93/15/EEC
Medical devices	93/42/EEC 98/79/EC
Potentially explosive atmospheres	94/9/EC
Recreational craft	94/25/EC
Lifts	95/16/EC
Refrigeration appliances	96/57/EC
Pressure equipment	97/23/EC
Telecommunications terminal equipment	98/13/EC
In vitro diagnostic medical devices	98/79/EC
Radio and telecommunications terminal equipment	99/5/EC

Essential requirements set up by New Approach directives may overlap or complement each other, depending on the hazards covered by these requirements that are related to the

product in question. The placing on the market and putting into service can only take place when the product complies with the provisions of all applicable directives, and when the conformity assessment has been carried out in accordance with all applicable directives. The Directive on product liability (85/374/EEC) is applicable to all products covered by New Approach directives.

The Role of harmonised standards

Harmonised European standards are European standards, which are adopted by European standards organisations, prepared in accordance with the General Guidelines agreed between the Commission and the European standards organisations, and follow a mandate issued by the Commission. Harmonised standards in the meaning of the New Approach are deemed to exist when the European standards organisations formally present to the Commission the European standards elaborated or identified in conformity with the mandate. Harmonised standards are not a specific category amongst European standards. The terminology used in New Approach directives is a legal qualification of technical specifications existing as European standards, but to which a special meaning has been given by these directives. Harmonised / mandated standards maintain their status of voluntary application in the field of New Approach directives. However it can be assumed that the basic requirements of a directive are fulfilled if the requirements of a harmonised / mandated European standard are fulfilled.

Modules of Conformity assessment

Before placing a product on the Community market, the manufacturer must subject the product to a conformity assessment procedure. The key elements in this respect are the building of confidence through competence and transparency, and the setting up of a comprehensive policy and framework for conformity assessment. The Council Resolution of 1989 on the Global Approach to certification and testing states the following guiding principles for Community policy on conformity assessment:

- A consistent approach is developed in Community legislation by devising modules for the various phases of conformity assessment procedures, and by laying down criteria for the use of these procedures, for the designation of bodies operating these procedures, and for the use of the CE marking.
- The use of European standards relating to quality assurance (EN ISO 9000 series), and to the requirements to be fulfilled by conformity assessment bodies operating quality assurance (EN 45000 series) is generalised.
- Setting up of accreditation systems and the use of inter-comparison techniques are promoted in Member States and at Community level.

Conformity assessment is subdivided into modules, which comprise a limited number of different procedures applicable to the widest range of products. The modules relate to the design phase of products, their production phase or both. The eight basic modules and their eight possible variants can be combined with each other in a variety of ways in order to establish complete conformity assessment procedures.
Each New Approach directive describes the range and contents of possible conformity assessment procedures, which are considered to give the necessary level of protection. The directives also set out the criteria governing the conditions under which the manufacturer can make a choice, if more than one option is provided for.
Thus in general conformity assessment is based on manufacturers' internal design and production control activities and independent third party testing. However in most cases the

conformity assessment is just a self assessment of the producer and no independent third party conformity assessment is needed. This is in line with the European Commission's policy on laying more emphasis on product liability for the producer.

Table 2 Modules of conformity assessment (providing for CE marking)

Basic modules	**Description**
A Internal control of production	Covers internal design and production control. This module does not require a notified body to take action.
B EC type-examination	Covers the design phase, and must be followed up by a module providing for assessment in the production phase. The EC type-examination certificate is issued by a notified body.
C Conformity to type	Covers the production phase and follows module B. Provides for conformity with the type as described in the EC type-examination certificate issued according to module B. This module does not require a notified body to take action.
D Production quality assurance	Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9002, with the intervention of a notified body responsible for approving and controlling the quality system for production, final product inspection and testing set up by the manufacturer.
E Product quality assurance	Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9003, with the intervention of a notified body responsible for approving and controlling the quality system for final product inspection and testing set up by the manufacturer.
F Product verification	Covers the production phase and follows module B. A notified body controls conformity to the type as described in the EC type-examination certificate issued according to module B, and issues a certificate of conformity.
G Unit verification	Covers the design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.
H Full quality assurance	Covers the design and production phases. Derives from quality assurance standard EN ISO 9001, with the intervention of a notified body responsible for approving and controlling the quality system for design, manufacture, final product inspection and testing set up by the manufacturer.

Notified Bodies

Notified bodies carry out the tasks pertaining to the conformity assessment procedures referred to in the applicable New Approach directives when a third party is required. Member States are responsible for their notification. They may choose the bodies they notify from the bodies under their jurisdiction which comply with the requirements of the directives and the principles laid down in Decision 93/465/EEC. The assessment of the body seeking notification determines if it is technically competent and capable of carrying out the conformity assessment procedures in question, and if it can demonstrate the necessary level of independence, impartiality and integrity. Further, the competence of the notified body should be subject to surveillance, which is carried out at regular intervals and follows the practice

established by the accreditation organisations. The EN 45000 series of standards and accreditation are important instruments to help in establishing conformity with the requirements of the applicable directive.

Table 3 The EN 45000 series of standards relevant for notified bodies

	Certification bodies	Testing laboratories	Inspection bodies
Criteria for accreditation bodies	EN 45010	EN 45002 EN 45003	EN 45010
Accreditation and assessment criteria	EN 45010	EN 45002 EN 45003	EN 45010
Operational criteria	EN 45011 EN 45012 EN 45013	EN 45001	EN 45004

CE marking

Products in compliance with all provisions of the applicable directives providing for the CE marking must bear this marking. Thus, the CE marking is, in particular, an indication that the products comply with the essential requirements of applicable directives and that the products have been subject to a conformity assessment procedure provided for in the directives. It is mainly a means to promote trade, and it addresses the authorities of a member state.

DIN-Geprüft

The certification that gives producers the right to use the DIN-Geprüft (DIN Tested) mark is a voluntary one. The requirements for the certification are laid down in German Standards. Similar schemes exist in other Member States of the European Union, e.g. France (Marque NF).

Elements of certification

The elements of an independent product certification comprise the testing of the product for conformity and subsequently the monitoring of continuing conformity at regular intervals. Where provided for in the certification scheme, prior to the award of the certificate a first on-site inspection in which the production and testing facilities and the quality control procedures are reviewed in order to establish whether these are adequate for the purposes of proper manufacture. This first on-site inspection also serves to determine whether the production conditions are such as to ensure the continuing conformity of the products. The initial inspection involves a type test (prototype test) serving to establish whether the product complies with the requirements that are specified in German standards, and the relevant certification schemes.

Verification inspections serve to establish whether the product deriving from routine production corresponds to the product that was type-tested. These monitoring activities of specified scope are undertaken at given intervals. Conformity surveillance can be done by the manufacturer. In this case the manufacturer must ensure by way of suitable quality control measures that the product characteristics confirmed in the course of certification are maintained thereafter. This may be achieved by direct monitoring of the product or production process, supplemented by measures implemented in connection with a quality management system conforming to the DIN EN ISO 9000 series of standards. Conformity surveillance is also be done by the certification body by way of on-site inspections of the manufacturing and testing facilities and, where appropriate, the effectiveness of the quality management system. In addition to, or instead of, an on-site inspection, regular control testing of random samples of the product may be specified in the certification scheme.

Requirements for the certification body and laboratories

For each test performed, a test report is to be submitted that must at least conform with the specifications of DIN EN 45001 (DIN EN ISO 17025). The certification body has to comply with and be accredited against DIN EN 45011.

Comparison to CE-Mark

In contrast to the certification according to the new approach directives (CE-Mark) the certification for the German DIN-Geprüft mark is based on precise technical standards and not on relatively vague basic requirements of a European directive. It is aimed directly at the consumer, and the DIN-Geprüft mark shall raise the consumers confidence in a certified product. As mentioned above the DIN-Geprüft mark is mainly a national mark. In many member states of the European union exist other marks and certification schemes that are based on the conformity with national standards.

The Keymark

The Keymark is an approach to address the problem that many different marks for conformity with standards exist at the national level.

Meaning of the Keymark

The Keymark is a third-party certification mark for a product, demonstrating to users and consumers compliance of the product with the requirements of relevant European Standards. It is granted after the satisfactory completion of a certification procedure, comprising product conformity tests (initial type tests), assessment of the documented factory production control for the related production line, production site inspection and surveillance.

Ownership of the Keymark

The Keymark is a certification trade mark, the equally shared property of the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC).

Requirements for Certification Bodies Inspection Bodies and Laboratories

Certification Bodies implementing the CEN Keymark Scheme Rules shall be located in CEN member countries or countries of CEN-Affiliates which have implemented the relevant European Standards on Accreditation and shall be empowered by CEN Certification Board through the National Member Body. Certification Bodies shall fulfil EN 45011. All laboratories owned or employed by a Certification Body shall be accredited against EN 45001 (EN ISO/IEC 17025). Inspection activities operated by external bodies on behalf of the Certification Body, shall be accredited against EN 45004 as a third party.

The certification process

The certification process itself contains three elements, a factory production control, an initial testing and continuos surveillance.

Table 4 Elements of product certification (Keymark)

Elements of product certification	**Description**
Product related factory production control (FPC)	Precondition for the certification is the establishment and the operation of a product line related factory production control taking into account the elements of ISO 9000 and the process of the related production line from the raw material until the storage of the products. The factory production control has to be related at least to the characteristics covering aspects relevant for safety, if not specified otherwise in the reverence European Standard. The factory production control should form part of the manufacturer's quality management system.
Initial inspection and initial type test (ITT)	The initial inspection of the factory embraces a documentation of the kind of production taking into account the elements of ISO 9000 and the process(es) of the related production line(s) from the raw material until the storage of the products and includes the evaluation of the applied factory production control for the relevant production line and usually includes the sampling of products for the initial type testing. If not specified otherwise in the reference(s) European

	Standard at least one test sample has to been taken.
Surveillance procedures	The Certification Body and/or the test laboratory, which has already performed the initial type testing on behalf of the Certification Body, performs surveillance of the production and the product itself to ensure continued compliance with all the specified requirements for certification in accordance with these scheme rules.

Summary

The above mentioned certification schemes for consumer products in Europe differ in certain ways (details are given in Table 1). The mandatory system for the use of the CE mark is mainly focused on assuring free trade of products within Europe whereas the other systems are aimed at giving consumers more confidence in certified products.

Table 5 Comparison between CE mark, Keymark and DIN-Geprüft

	CE-Mark	**Keymark**	**DIN-Geprüft**
Regulatory framework	EU Directives	European Standards	German Standards
Product range	Limited to products for which EU directives exist	Limited to products for which European standards exist	Limited to products for which German standards exist
Technical requirements	• EU Directive • Harmonised / mandated European standard (if they exist) • National Standards (if no harmonised / mandated European standard exists)	• European Standard • (certification programs)	• German Standard • (certification programs)
Surveillance	By authorities of the member states	By the certification bodies	By certification body (DIN CERTCO)
Requirements for Notified Bodies or Certification Bodies	EN 45000 series of standards	EN 45011	DIN EN 45011
Mandatory / Voluntary	Mandatory	Voluntary	Voluntary