Das Know-how.

CE Summary

History - In the past many governments implemented various kinds of law or regulations to protect people against dangerous or faulty products. The differences between countries made it necessary to check the conformity to specific country law in each case. Very often the free product flow and market access was disabled and additional efforts were necessary to meet individual country regulations. National law of EU members was discussed and harmonized, leading to EC Directives which have to be transferred or modified in national law within a defined schedule.

In cooperation with
TÜO Technical Supervisory Organization

Learn targets

Description of the Topics

CE Marking
With the CE marking the manufacturer shows that his product satisfies the Essential Requirements applicable to it. Depending on the classification of the product the CE marking must be accompanied by the identification number of the Notified Body.

Manufacturer - The natural or legal person responsible for placing a product on the market, for fulfilling the relevant legal requirements, and for notifying the Competent Authorities of the Member States where incidents occur.

Notified Bodies - Independent auditing, certification and testing institutes for verification of product and quality systems as well as monitoring thereof.

Competent Authorities - The Competent Authority is the body which has the authority to act on behalf of the government of a Member State to ensure that the requirements of the Medical Device Directive are carried out in that particular Member State. Manufacturers or their authorised representatives are obliged to register with the Competent Authority in the country of their registered business and to specify the medical devices they are placing on the market. Among other things, the Competent Authority has to ensure that adverse incidents are reported within the appropriate timescales and are recorded and evaluated centrally.

Today - For the protection of the consumer or user, the EC Directives stipulate that products may only be brought onto a market if they comply with essential requirements of safety, health and other protection objectives. Compliance with these requirements shall be assured by adequate measures in the phases of design and production. Products with CE label generally are approved for sale in all EC membership countries. Some exceptions in non yet harmonized matters might occur.

Responsibility - Responsible for the attachment of the CE label is the first institution that introduces the product in the EC market, eg subsidiary, importer, sales representative etc.

Consequences - By transferring the Declaration of Conformity to manufacturer, governmental authorities give up fundamental rights of product control but remain responsible for safety and health of citizens. They are fully liable for any caused by misuse or abuse of the CE label. Therefore penalties are high. As the declaration is only valid for one unit, and only accepted to be copied for identical products in mass production this means theoretically that the penalty fee can be multiplied by the total number of units brought onto the market!

Every manufacturer should be aware of this high risk, which might hit him not only in a case of accident, but as well by claim of competitor or customer. The responsible authority must prosecute all cases of misuse or abuse. Since the Introduction of the European Single Market, the European Union (EU) has released essential EC Directives for safety, health and other protection objectives.

Selection of Harmonized EC Directives

73/23/EEC	Low voltage equipment	88/378/EEC	Safety of toys
89/336/EEC	Electromagnetic compatibility	89/392/EEC	Machinery
91/263/EEC	Telecom terminal equipment		

Duration of the workshop / seminar: 1 day

Don´t hesitate to ask for further information

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