AGENDA FOR THIS TOPIC

- Introduction to the EU and the law making process.
- What is CE marking?
- Directives and their identification.
- Ways OR routes OR modules to CE marking.
- Test standards and their identification.
- Technical documentation/file.
- Declaration of conformity (D.O.C).
- Market surveillance.
- Detailed description of modules.

BACKGROUND

- The EEC treaty
- The EFTA
- The EU treaty.
  - The objective
  - The Four Freedoms
- The EEA

IMPORTANT CONSIDERATIONS

- Who "gives" CE marking?
- Which products require CE marking'
- Who is responsible for CE marking?
  - **Manufacturer ?**
  - **Authorised Representative?**
  - **Importer? (or distributor/assembler/employer)**
- Charges/royalty/fee for using the CE marking?
- Whom is CE marking addressed to?
- Compliance with what?
- Are there legal implications?

MORE ON SELF-DECLARATION.

Self-declaration is a process in which

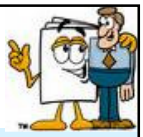
The manufacturer himself/herself ensures that the product meets essential requirements.

He himself declares conformity through a document called as **Declaration Of Conformity** (D.O.C).

Manufacturer himself affixes CE marking on the product.

To take care of false CE Marking there exists a process of Market Surveillance to weed out non-compliant products

CE MARKING PROCEDURE



DESIGN PHASE

- Identify applicable directives.
- Identify module (route).
- Identify applicable 'EN' Standards.
- Comply with tests and evaluations.

PRODUCTION PHASE

- Sign "Declaration of conformity(DOC)".
- Affix "CE" marking.

EMC – Directive 2014/30/EC



- Covers "Electromagnetic-Compatibility" i.e. Emission + Immunity. The directive is in force since 20.4.2016 and is applicable to electrical equipment.
- Essential requirement:

Equipment should not emit ElectroMagnetic Interference (EMI) above a certain limit and shall be immune to EMI generated by other equipment.

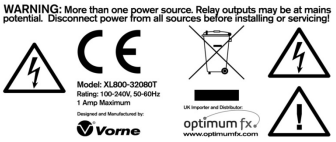
ROUTES TO CONFORMITY

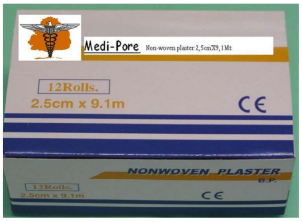
DESIGN PHASE	PRODUCTION PHASE
Internal Production Control (Module 'A')	
EC Type Examination (Module'B')	+ Conformity to Type (Module 'C')
	+ Production Q.A (Module 'D')
	+ Product Q.A (Module 'E')
	+ Product Verification (Module 'F')
UNIT Verification (Module 'G')	
Full Q.A (Module 'H')	

TESTING OF PRODUCT

- Conformance with a standard gives *presumption of conformity* with the directive.
- It is the most acceptable way to demonstrate compliance to essential requirements of the directives.
- Application of standards remains voluntary.
- All tests according to standards must for Module 'A'.
- Testing can be done in-house or from a 3rd party test Lab.
- Verify credibility of external lab (Accreditation?).

AFFIXING "CE" MARKING



RAPID INFORMATION EXCHANGE (RAPEX)

This is a N/W of linked servers for exchange of information

- As soon as a product is deemed dangerous by one member state, the national authority there takes appropriate action to eliminate the risk.
- The information is conveyed on-line to the commission which is transmitted rapidly to the other member nations.
- The national authorities in those nations then take similar measures in their region.
- In this way, the entire community market is protected from dangerous products