

CE Marking of Machinery

- Introduction -



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The 4 freedoms of the Common Market

Free Movement of Persons

- No border control
- Harmonisation of legislation
- Free establishment and free choice of working place
- Stronger controls at EU borders

Free Movement of Services

- Liberalisation of financial services
- Harmonisation of surveillance of banks and insurances
- Opening of transport- and telecommunication markets

EUROPEAN INTERNAL MARKET

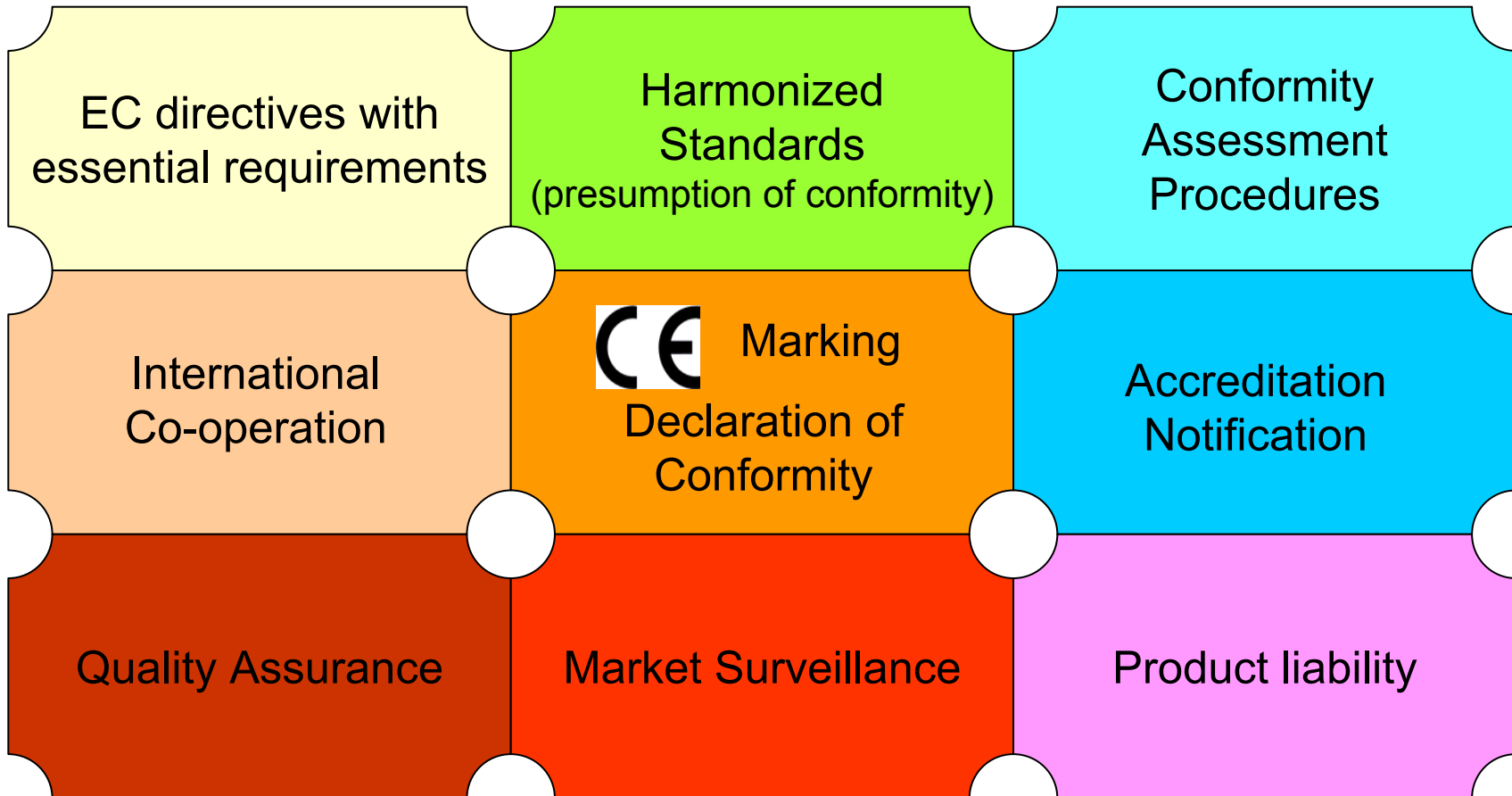
Free Movement of Goods

- No border control
- Harmonisation and mutual recognition of standards and legislation
- Tax harmonisation

Free Movement of Capital

- More free movement for money and capital
- Steps towards a common market for financial services
- Liberalisation of movement of bonds

Elements of the „New and Global Approach“



What are the products concerned? Which directives require CE marking?

Electrical equipment (Low Voltage Directive)	2006/95/EC (old 73/23/EEC)
Electromagnetic compatibility	2004/108/EC (old 89/336/EEC)
Machinery	2006/42/EC (old 98/37/EC)
Simple pressure vessels	87/404/EEC
Toys	88/378/EEC
Construction products	89/106/EEC
Personal protective equipment	89/686/EEC
Non-Automatic Weighing instruments	90/384/EEC
Active implantable medical devices	90/385/EEC
Gas appliances	90/396/EEC
Hot water boilers (Energy efficiency)	92/42/EEC
Civil explosives	93/15/EEC

What are the products concerned? Which directives require CE marking?

- Medical devices 93/42/EEC
- Products for potentially explosive atmospheres 94/9/EC
- Recreational crafts (boats) 94/25/EC
- Lifts 95/16/EC
- Refrigeration appliances (Energy efficiency) 96/57/EC
- Fluorescent lighting (Energy efficiency) 2000/55/EC
- Pressure equipment 97/23/EC
- Telecommunications terminal Equipment 1999/5/EC
- In vitro diagnostic medical devices 98/79/EC
- Cableway installations 2000/9/EC
- Measuring instruments 2004/22/EC
- Eco-design requirements for energy-using products 2005/32/EC
- Pyrotechnic articles 2007/23/EC

Other Directives - based on New Approach - not requiring CE

- Packaging and packaging waste 94/62/EC
- Interoperability of high-speed rail system 96/48/EC
- Marine equipment 96/98/EC
- Interoperability of conventional rail system 2001/16/EC
- Transportable pressure equipment 1999/36/EC
- Noise emission by equipment for use outdoors 2000/14/EC

- **General Product Safety directive 2001/95/EC**

CE marking process

Who is / can be responsible?

1. The manufacturer

- The person who is responsible for designing and manufacturing a product with a view of placing it on the Community market on his own behalf.
 - » In practice: under his own name

2. Authorised Representative

- If manufacturer is not established in the EU, though not mandatory

3. Importer

4. Distributor

5. Assembler and Installer

6. Operator (User)

- Harmonised Standards with presumption of conformity
 - Worked out on basis of EU-Mandate
 - Official list published in Official Journal of EU (regularly updated)
 - Internet-Source (harmonised and mandated Standards):
www.newapproach.org
 - Application remains **voluntary**
- National or international standards and technical Specifications
 - Application in all fields, where (still) no harmonised standards are existing
- Quotation in EC-Declaration of Conformity or in Manufacturer's Declaration
 - Recommendation: Standards, which requirements are fully met (total compliance)



New Approach Standardisation in the Internal Market

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- Directives & Standards
- Product Families and Keywords
- Questions & Answers
- Standards Sales Points



Directives & Standards					
Directive reference	Subject of directive	Info about directive	Standards activities	References harmonised standards	
90/396/EEC	Appliances burning gaseous fuels	▶	▶	▶	
90/9/EC	Cableway installations designed to carry persons	▶	▶	▶	
89/106/EEC	Construction products	▶	▶	▶	
89/336/EEC	Electromagnetic compatibility	▶	▶	▶	
94/9/EC	Equipment and protective systems in potentially explosive atmospheres	▶	▶	▶	
93/15/EEC	Explosives for civil uses	▶	▶	▶	
95/16/EC	Lifts	▶	▶	▶	
73/23/EEC	Low voltage equipment	▶	▶	▶	
98/37/EC	Machinery safety	▶	▶	▶	
2004/22/EEC	Measuring instruments		▶		
90/385/EEC	Medical devices: Active implantable	▶	▶	▶	
93/42/EEC	Medical devices: General	▶	▶	▶	
98/79/EC	Medical devices: In vitro diagnostic	▶	▶	▶	
92/42/EEC	New hot-water boilers fired with liquid or gaseous fluids (efficiency requirements)		▶	▶	
90/384/EEC	Non-automatic weighing instruments		▶	▶	

Publication of harmonised Standards

Enterprise - New Approach - Harmonised standards: List of directives and subjects - Microsoft Internet Explorer

Datei Bearbeiten Ansicht Favoriten Extras ?

http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist.html



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HARMONISED STANDARDS

LIST OF DIRECTIVES AND SUBJECTS

- New Approach directives (directives providing for CE marking)** >>> [view](#)
- Directives based on the principles of the New Approach or the Global Approach, but which do not provide for CE marking** >>> [view](#)
- Directives based on some principles of the New Approach and the Global Approach** >>> [view](#)
- Other standards-receptive directives** >>> [view](#)

New Approach directives (directives providing for CE marking)

Text of directive and amendments	Consolidated version of directive	Subject (short title of directive) Lists of references of harmonised standards and general information
2006/95/EC		Low Voltage
87/404/EEC 90/488/EEC 93/68/EEC	87/404/EEC	Simple Pressure Vessels
88/378/EEC 93/68/EEC	88/378/EEC	Safety of toys

- All the bodies, which are officially notified on EU level, are registered in the **NANDO** (New Approach Notified and Designated Organisations) information system. It is available for the general public under the following website:

<http://ec.europa.eu/enterprise/newapproach/nando>