

## PROJECT MEDOCE

# THE IMPORTANCE OF CE MARKING FOR SME 'S - WKÖ EXPERIENCE

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## WHY EUROPEAN TECHNICAL STANDARDS ?

- The EU Single Market offers free movement of goods (without national technical barriers) in Europe, with high safety targets
- The high safety targets per product category are defined by European legislation, and specified (technically) by European standardisation bodies.
- One European directive and standard replace 30 national laws and standards!

## EU LAW AND EUROPEAN STANDARDISATION

- EU legislation = directives, regulations  
→ binding
- European Standards (EN)  
→ not binding, but helpful as many standards lead to "assumption of conformity"

## DEVELOPMENT OF EUROPEAN STANDARDS

- technical standards are developed by standardisation bodies (private undertakings, not legislative body)
- Enterprises can nominate experts for standards committees
- European standards are developed by enterprises, technical experts, SMEs and consumer representatives

## NEW APPROACH (CE-MARK-DIRECTIVES)

- EU directive defines the basic legal requirements on product safety (risk prevention),
- risks related to product, e.g. moveable parts in machines, electrical risks, pressure risks...
- EU commission can give mandate to CEN to develop standards:
- the technical details/procedures how to eliminate the risks are developed by CEN
- European harmonised standards are published in EU official Journal

## EU „NEW APPROACH“



- CE-mark: affixed by the manufacturer to certify that the product meets the requirements of the applicable directive(s), by applying harmonised technical standards or equivalent technical solutions

## EU „NEW APPROACH“ VS. „OLD APPROACH“ IN TECHNICAL LEGISLATION

- Not all products for EU market bear CE-mark (only those which fall under a specific directive – currently 25).
- Other products (e.g. cars, pharmaceuticals, food...) are regulated in all technical details by specific directives ("old approach")

## TECHNICAL STANDARDS FOR PERSONAL SKILLS

Personal skills are standardised - among others – for:

- quality system and internal manufacture checks (quality manager, assistant)  
(many EU directives provide for full quality assurance, sometimes with external surveillance by notified bodies)
- welding expert & welding supervision  
(for construction products - e.g. steel and aluminium structures, EN 1090- , special personal skills may be required by law, e.g. welding experts who are certified according to European welding standards)



## EU DIRECTIVE ON HEALTH AND SAFETY AT WORK

- all kinds of workplaces must be safe (offices, construction sites, industry plants...)
- working equipment/tools (machinery, vehicles, clothing...) must comply with EU product safety standards (e.g.: CE mark for machinery and personal protective equipment)
- Enterprises must designate "safety persons" for worker's protection and prevention of accidents

## BINDING APPLICATION OF EU LAW

- EU directives & regulations are binding for all member states (and some closely associated states)
- EU law becomes part of national law:
  - All enterprises are subject to EU law (even enterprises only active in their home market!)
- CE-mark directives, other technical directives, directive on Health and Safety at work (and others) are also applicable to SMEs that do not export to other EU countries

## CE MARK AS CHALLENGE FOR SMES

- most SMEs do not have enough regulatory & technical expertise to do conformity assessment on their own
- increasing China imports: small traders have limited knowledge of EU product safety requirements
- → external support (by Chambers etc.) is key

## EU-SERBIA STABILISATION AND ASSOCIATION AGREEMENT

### Art. 77 (Standardisation, metrology, conformity assessment)

1. Serbia shall take the necessary measures in order to gradually achieve conformity with Community technical regulations and European standardisation, metrology, accreditation and conformity assessment procedures.
2. To this end, the Parties shall seek to:
  - (a) promote the use of Community technical regulations, European standards and conformity assessment procedures;

## EUROPEAN STANDARDS ARE IMPORTANT FOR:

- Access to EU market: any product put on the EU market must meet the EU technical requirements (in most cases, Standards are available and highly recommended - because of "assumption of conformity")
- in case of construction products: product standards plus personal skills Standards are compulsory
- Public Tenders usually demand that tenderers must comply with technical Standards as specified in tender dossier (including personal skills and quality system)
- Once a candidate Country joins the EU, EU legislation and Standards are fully applicable to national market (even for companies that do not export to other EU countries)

**THANK YOU FOR YOUR ATTENTION!**

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