New Pressure Equipment Directive 2014/68/EU

Presented by Dirk Schroeter
Welcome

• **Webinar ground rules**
  - All conference call participants have been muted to allow a clear connection to our facilitator
  - Questions can be submitted via online chat room
  - Most questions will be answered at the end of the presentation
  - Please send unique/company specific questions to the presenter via e-mail
  - For a copy of this presentation, please contact webinar@tuvam.com

• **Housekeeping**
  - The presentation will run for approximately 30 minutes with 15 minutes for questions and answers
TÜV SÜD in numbers: Growing from strength to strength

1. One-stop technical solution provider
2. 150 years of experience
3. 800 locations worldwide
4. 1,900 million Euro in sales revenue 2013
5. 20,200 employees worldwide
Global expertise. Local experience.

Legend:
- Countries with TÜV SÜD offices
- Regional headquarters

Note: Figures have been rounded off.
TÜV SÜD America Inc., founded in 1987, is the North American subsidiary of TÜV SÜD AG.

TÜV SÜD America Inc. provides complete services through its divisions:

- Product Service
- Management Service
- Industry Service
- Chemical, Oil and Gas
- Global Risk Consultants
New Pressure Equipment Directive 2014/68/EU

- **Pressure Equipment Directive 97/23/EC**
  - Signed May 29, 1997
  - Published July 09, 1997
  - First time use November 29, 1999
  - Mandatorily to be applied for manufacturer May 29, 2002

- **New Pressure Equipment Directive 2014/68/EU**
  - Signed May 15, 2014
  - Published June 27, 2014
  - First time use July 17, 2014 (entry into force of 2014/68/EU)
  - Parts of 2014/68/EU mandatorily to be applied June 01, 2015
  - 2014/68/EU (entirely) mandatorily to be applied July 19, 2016
New Pressure Equipment Directive 2014/68/EU

• Keep in mind: both Pressure Equipment Directive 97/23/EC and New Pressure Equipment Directive 2014/68/EU are LAWS

  – Some of the important aspects of the laws with regards to the changes

    • Products placed on the European Market or make them available for use on the European Market: it needs to ensure a high level of protection of public interests, such as health and safety of persons, and the protection of domestic animals and of property

    • Fair competition on the Union market

    • Roles and responsibilities are defined

    • Liability

    • Enforcement and market surveillance
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• **Safety Aspects**
  
  – Identified in Annex I
    
    • Only updates of references to Articles and Annexes
    
    • No technical changes
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- Roles and Responsibilities
  - Addressed to:
    - European Commission
    - Member States
      - National Accreditation Bodies
    - Economic Operators
      - Manufacturer
      - Authorized representative
      - Importer
      - Distributor
    - Assessment Bodies
      - Notified Bodies
      - Third-Party Organizations
      - User Inspectorates
Roles and Responsibilities

- Economic Operators shall on request identify the following to the market surveillance authorities
  - Any economic operator who has supplied them with pressure equipment or an assembly
  - Any economic operator to whom they have supplied pressure equipment or an assembly

- Manufacturer
  - Make sure Annex I requirements are fulfilled (product is safe)
  - Or sound engineering practices of a Member State have been applied (in case of product falling under Article 4(3) (formerly Article 3(3)))
  - Draw up the technical documentation
  - Shall keep technical documentation and EU declaration of conformity for 10 years after pressure equipment or assemblies have been placed on the market
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• Roles and Responsibilities
  – Manufacturer
    • Keep a register of complaints of non-conforming pressure equipment and assemblies and recalls
    • Carry out sample testing of pressure equipment or assemblies made available on the market
    • Ensure that pressure equipment is accompanied by instructions and safety information (Annex I Section 3.3 and 3.4) in a language which can be easily understood by consumers and other users, as determined by the Member State concerned.
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• Presumption of Conformity
  – No changes

• Classification of Pressure Equipment
  – Modified: change needs to be applied latest June 01, 2015
  – New regulation 1272/2008 for classification of fluids
Records and correspondence relating to conformity assessment procedures shall be drafted in an official language of the Member State where the body responsible for carrying out these conformity assessment procedures is established, or in a language accepted by that body.
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• EU Declaration of Conformity
  – Shall be translated into the language or languages required by the Member State in whose market the pressure equipment or assembly is placed or made available on the market
  – Annex IV (was Annex VII)
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- **Union Market Surveillance, Control of Pressure Equipment and Assemblies entering the Union Market, and Union Safeguard Procedure**
  - Safeguard procedure (was already existing)
  - Compliant pressure equipment or assemblies which present a risk
  - Formal non-compliances
    - CE marking has not been affixed
    - Notified Body number wrong or missing (if applicable)
    - Marking not correct
    - Missing or wrong Declaration of Conformity
    - Technical documentation not available or not complete
    - ...
Existing PED Certificates / Approvals

- **Existing PED Certificates / Approvals**
  - Article 48 Section 3: Certificates and decisions issued by conformity assessment bodies under Directive 97/23/EC shall be valid under this Directive
  - **However: Pressure Equipment needs to comply with new Directive 2014/68/EU**
  - Classification of pressure equipment and assemblies under existing certificates / approvals need to be re-visited prior June 01, 2015
  - Module A1 and Module C1 will be transitioned to Module A2 and Module C2 respectively Q2/2015 after the Unexpected Visit
  - Module B1 and Module B will need to be transitioned to Module B (design type) and Module B (production type) respectively
Existing PED Certificates / Approvals

- **Existing PED Certificates / Approvals**
  - Quality System Approvals Module D/D1, E/E1, H/H1
    - After the next surveillance / re-certification quality system audit TÜV SÜD will identify both versions of the PED on the certificate – providing certificate holder updated quality system documentation to reflect the changes
    - Audits after June 01, 2015 will mandatorily need to address classification of fluids
    - Last audit prior July 19, 2016 will need to address all aspects of 2014/68/EU
Questions?
Contact us today

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