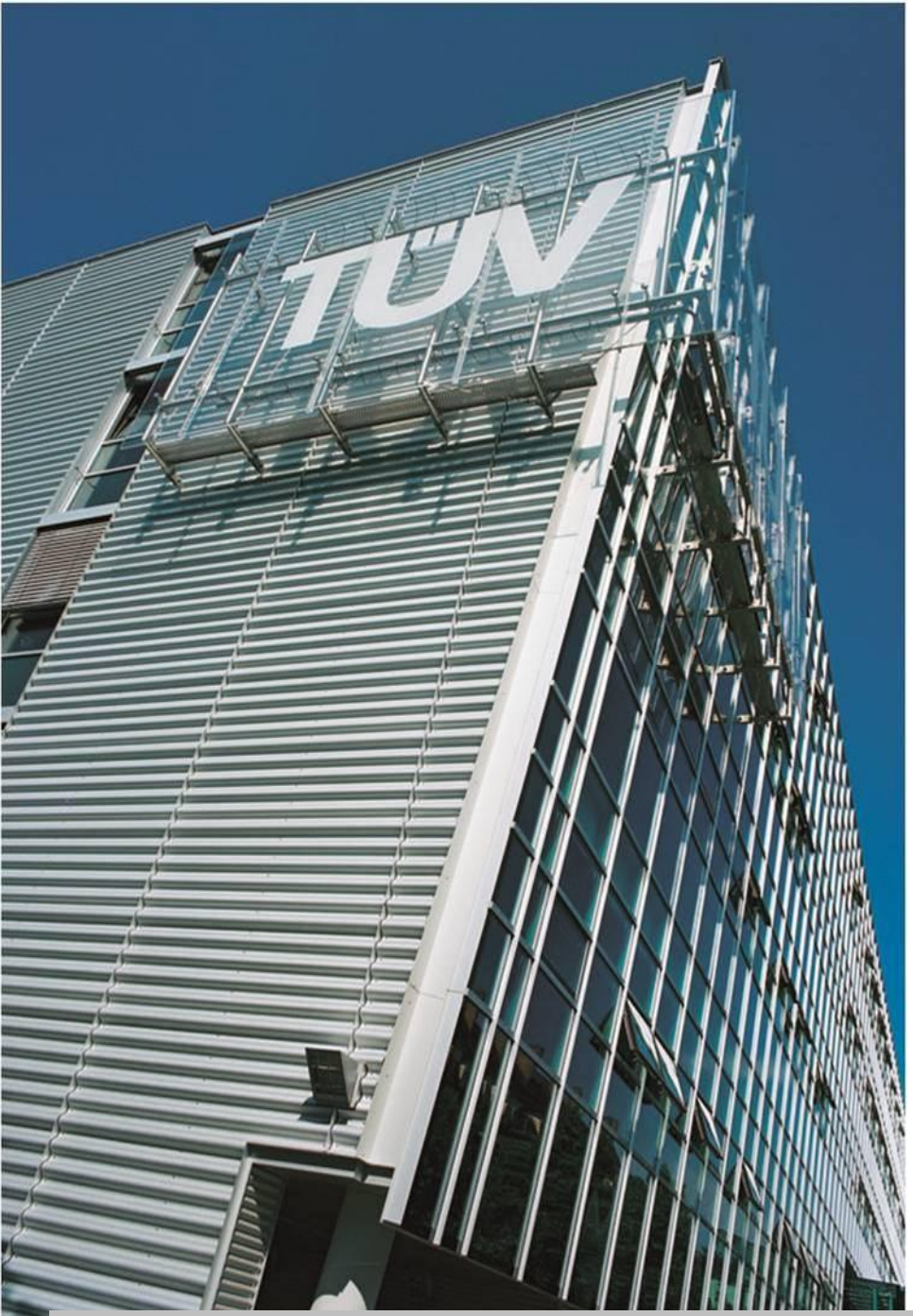

Product Service

Mehr Sicherheit.
Mehr Wert.

AHWP November 2015
Bangkok, Thailand

Hans-Heiner Junker
TÜV SÜD Product Service
Munich, Germany

Disclaimer

The new regulations are not finalzied, yet, and subject to changes

Introduction

~~Declaration of Conformity~~

~~According to 93/42/EEC~~

Declaration of Conformity

According to ??? (MDR)

~~CE 0123~~

CE 0123

The Pathway

- **A new regulation – no directive**
  - **from AIMD/MDD/IVDD to MDR/IVDR**
- **Where are we in the process? What is a "trialogue"**
  - **European Commission**
  - **European Parliament**
  - **Council of Member states**
- **6 meetings are expected until end of 2015**
- **Additional technical meetings are taking place**
- **Final version not clear, yet.**
- **When to expect publication of new MDR & IVDR?**

Whow needs to adopt to the changes?

- **All existing Notified Bodies will loose their status as Notified Body**
- **All organizations who want to *become* a Notified Body for medical devices need to *apply* for a new Designation**
- **All manufacturers need to comply with the new regulations after a transition period**

What does that mean?

- **All existing EC-certificates issued by a Notified Body and based on 90/385/EEC, 93/42/EEC or 98/78/EC will expire after a transition period**
- **All manufacturers who want to CE-mark their products after a transition period (all classes) need to assess whether their products are in compliance with the Essential Requirements**
- **All manufacturers who need a Notified Body for their conformity assessment procedure need to apply for certification according to the new regulation**

What does that mean? Cont

- **After successful completion of the new conformity assessment process manufacturers have to issue a new Declaration of Conformity**
  - **If applicable: a newly designated Notified Body needs to be involved and needs to issue a new EC certificate as part of the conformity assessment**
- **Only after the issuance of this new declaration of conformity products can be CE-market and place on the European market**

What to expect? Technical Documentation

- **Technical Documentation is one of the most important part of the all Conformity Assessment procedures, and**
- **needs to comply with the *new requirements***
  - **As the content of the essential requirements will change, the content of the technical documentation needs most likely an update**

Language Requirement

"The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language(s) determined by the Member State concerned. "

"Otherwise they shall be available in an official Union language acceptable to the notified body."

What to expect? Chain from Manufacturer to End User

- **Economic Operators are importers, dealers, European representatives, and manufacturers**
- **“For devices, other than custom-made or investigational devices, economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 8(4):**
  - **any economic operator to whom they have supplied a device;**
  - **any economic operator who has supplied them with a device;**
  - **any health institution or healthcare professional to whom they have supplied a device.**

  Upon request, they shall inform the competent authorities thereof. “

What to expect?

- **UDI Codes:**
  - **products will be marked with an UDI code**
  - **this code deviates, up to now, from the systems used in other countries**

- **Prodcut registration:**
  - **European database for various information is called: EUDAMED**
  - **EUDAMED will also become the database for product registration in Europe**
  - **Notified Bodies reported their certificates already to EUDAMED**

Few comments on IVDR

- **Very similar to MDR**
- **New: classification based on risks**
- **Classes A, B, C, and D**
- **Conformity assessment preocedures based on this classification**
- **Most likely 5 years transition period**

Thanks for listening

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