The new EU MDR – lessons learned from the past

Engaging with the new EU regulatory landscape for medical devices.
Challenges & opportunities

Brussel, Belgium
April 6, 2018

Per Kjaersgaard-Andersen
Associate Professor
Section for Hip and Knee Replacement, Vejle Hospital, Denmark
&
1. Vice-president, EFORT
Past challenges

• Christiansen hip prosthesis
• Boneloc cement
• MoM bearings
• Modular neck in THA
Not to forget

• **Design problems**
  – Ceramic inlay with elevated metal rim
  – Stable fixation of coatings

• **Instruments**
  – Safely use for surgeons and patients
  – Fit the final implant (tolerance)
Goals in EFORT

• Support safe and timely treatment of all patients in the European Orthopaedic Community

• In the world of multiple implant options, EFORT support and will ask to be involved in initiatives to guide colleagues and authorities in selecting the best and most safe implant solution for our patients
Goals in EFORT

• EFORT therefore look for initiatives to improve patients treatment – and to reduce complexity when judgment of a given implant is needed.

• EFORT welcome all initiatives where patients safety is in front.