Laws, Regulations and Standards

Industry challenges and opportunities for the medical device sector in Europe

Holger Schmidt
COCIR Board Member and Corporate Vice President Quality at Siemens Healthineers
Patient safety is a high priority for all of us...

However, our industry is struggling with many regulatory obligations from various countries not necessarily converging ...
Innovation is driving our business, continuously improving “state-of-the-art”.

Does “state-of-the-art” depend on the price point?
Standardization supports patient safety

Can you imagine to operate this safely and seamless without technical standards?

Security standards will play important role in digitalization of healthcare.

Europe needs to actively drive global standards and support regulatory acceptance.
Regulations should be viewed holistically

Impact needs to be quantified and monitored.
COCIR Vision

APPROVED ONCE

ACCEPTED EVERYWHERE
Thank you