The digital transformation of the healthcare sector has been an important driver for improving a broad range of outcomes, including innovative medical products. Artificial intelligence (AI), especially machine learning (ML), are opening up new frontiers in medicine but are also leading to unprecedented challenges associated with regulating their use. New regulatory approaches supporting the introduction of new technologies are needed: The parallel development of technology and regulation under real-world conditions, for example, takes a practical approach to realising policy goals.

Metrology can make a valuable contribution to regulation. Quality metrics and reference data developed by metrology for example can support an objective and impartial evaluation of algorithms and thus strengthen the social acceptance of the use of AI.

This workshop will discuss the role of metrology in supporting modern approaches to regulation that are compatible with current software development processes. The focus will be on the requirements that Regulations (EU) 2017/745 on medical devices, (EU) 2017/746 on in vitro diagnostic medical devices, and the proposed European Regulation on establishing harmonised rules for artificial intelligence (Artificial Intelligence Act) are setting for medical devices with a high software content (especially AI).

Key questions on the role of metrology are:
• How will emerging technologies be regulated in the future?
• How can metrology contribute to clear guidelines and procedural instructions for medical devices with a high software content in order to check the quality of the data and the (AI) procedures?
• How can metrology be efficiently integrated into agile regulation methods?