MDR - European Medical Device Regulation Roles & Responsibilities

European Commission

Issuing European regulations
Orchestrating Operational Work of Notified Bodies by Oversight group (NBO)
Coordinating Designation of Notified Bodies via Joint Assessment Teams (JAT)
Issuing Mandates for the European Standardization Bodies (CEN/CENELEC)
Involving Harmonized Standards Consultants (HAS) before Harmonization

Member States

Transposing requirements into national legislation

National Competent Authorities

Supervising Notified Bodies within their Member State

Notified Bodies

Performing Conformity Assessments
organized in TEAM-NB

Represented by

Michael Bothe, Head of NB AMD