MIS À JOUR LE 15/12/2025

Règlementation des DM et DMDIV relative aux investigations cliniques et aux études des performances

Textes communautaires

Règlement européen et guides associés encadrant les investigations cliniques des DM

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)Text with EEA relevance
- Regulation (EU) 2027/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- MDGC Guidances

Réglementation française

- Textes applicables aux **RIPH UNIQUEMENT**