

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**