MIS À JOUR LE 25/05/2021

Règlementation des DM et DMDIV relative aux investigations cliniques et aux recherches impliquant la personne humaine

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
- MDGC Guidances
- MDCG 2021-6: Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation
- MDCG 2019-9: Summary of safety and clinical performance – August 2019
- MDGC 2020-5: Guidance on clinical evaluation – Equivalence – April 2020
- MDGC 202-10/2: Guidance on safety reporting in clinical investigations – May 2020
- MDGC 2020-10/1: Appendix: Clinical investigation summary safety report form - May 2020

Réglementation française

- Textes applicables aux **RIPH UNIQUEMENT**