Key documents

Recommendations

- Commission Recommendation 2013/172/EU of 5 April 2013 on a common framework for a unique device identification system for medical devices in the Union
- Commission Recommendation 2013/473/EU of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices

Classification

- Commission Recommendation of 24 September 2013 - OJ L 253/27 of 25 September 2013
- Reclassification of hip, knee and shoulder joint replacements:
  - Directive 2005/50/EC - OJ L 210/41 of 12 August 2005
- Reclassification of breast implants:
  - Directive 2003/12/EC - OJ L 28/43 of 04 February 2003

Other amending and implementing legislation

- Designation and the supervision of notified bodies:
  - Commission Implementing Regulation (EU) 2020/666 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies – OJ L 153 of 10 May 2020
- Common technical specification on IVDs:
  - Commission Implementing Decision (EU) 2020/350 - OJ L 63 of 3 March 2020
  - Commission Implementing Decision 2019/1244/EU - OJ L193/1 of 19 July 2019
  - Commission Decision 2011/869/EU - OJ L341/63 of 22 December 2011
  - Corrigendum to Commission Decision 2009/886/EC - OJ L 348/94 of 29 December 2009
  - Commission Decision 2009/886/EC - OJ L318/25 of 14 December 2009
- Qualification of products depending on proanthocyanidins present in cranberry
  - Commission Implementing Decision (EU) 2017/1445 – OJ L 207 8 August 2017
- Eudamed2 - European databank on medical devices:
  - Commission Implementing Regulation (EU) No 920/2013 - OJ L 523 of 25 September 2013
  - Commission Decision 2010/227/EU - OJ L102/45 of 23 April 2010
- Medical devices manufactured utilising tissues of animal origin:
  - Commission Regulation (EU) No 722/2012 - OJ 212/3 of 09 August 2012
  - Directive 2003/32/EC - OJ L105/18 of 26 April 2003
- Electronic instructions for use of medical devices:
  - Commission Regulation (EU) No 207/2012 - OJ L72 of 10 March 2012
- Variant Creutzfeld-Jakob disease assays:
  - Commission Directive 2011/100/EU - OJ L341/50 of 22 December 2011
  - Commission Decision 2002/364/EC - OJ L131/17 of 16 May 2002