

## 含動物來源之醫療器材法規

- Guidelines on assessment of medical devices incorporating materials of animal origin with respect to viruses and transmissible agents. European commission MEDDEV 2.5-8 rev. 21999.
- Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices). FDA CDRH Draft guidance,2014.
- Active implantable medical devices and medical devices manufactured utilizing tissues of animal origin. EU Commission Regulation No. 722, 2012.
- Medical devices utilizing animal tissues and their derivatives -Part 1: Application of risk management. ISO 22442-1, 2015.
- Medical devices utilizing animal tissues and their derivatives -Part 2: Controls on sourcing, collection and handling. ISO 22442-2,2015.
- Medical devices utilizing animal tissues and their derivatives -Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents. ISO 22442-3, 2007