The current Medical Device Directive (MDD) defines the classification rules for medical devices in Annex IX (http://bit.ly/M5MDD). In the proposed EU regulations (http://bit.ly/EURegs), the classification rules are now in Annex VII. The current MDD has 18 rules, while the proposed regulations have 21 rules.

The following is a comparison (i.e., – gap analysis) of the classification rules:

1. No change to this rule.
2. No change to this rule.
3. This rule was expanded to include IVF and ART devices, which are Class IIb devices.
4. No change to this rule.
5. No change to this rule.
6. No change to this rule.
7. No change to this rule.
9. Devices intended to control, monitor or directly influence active implantables are reclassified from Class IIb devices to Class III devices.
10. No change to this rule.
11. No change to this rule.
12. No change to this rule.
13. No change to this rule.
14. No change to this rule.
15. No change to this rule.
16. This rule was expanded from X-Ray imaging to include MRI & ultrasound.
17. Minor changes in the rule, but no reclassification.
18. No change to this rule.
19. This rule is new and specific to nanomaterials. These are Class III devices.
20. This rule is new and specific to apheresis machines, sets, connectors and solutions. These are Class III devices.
21. This rule is new and specific to combination products. The closest existing regulation is rule 13. These are Class III devices.
Gap Analysis of Classification Rules for CE Marking

About the Author

Robert Packard is a regulatory consultant with 20 years experience in the medical device, pharmaceutical and biotechnology industries. He is a graduate of UConn in Chemical Engineering. Robert was a senior manager at several medical device companies—including President/CEO of a laparoscopic imaging company. His Quality Management System expertise covers all aspects of developing, training, implementing, and maintaining ISO 13485 and ISO 14971 certification. From 2009-2012, he was a lead auditor and instructor for one of the largest Notified Bodies. Robert’s specialty is regulatory submissions for high-risk medical devices, such as implants and drug/device combination products for CE marking applications, Canadian medical device applications and 510(k) submissions.

If your company would like additional training on the CE Marking process, including formatting and content of a Class III Design Dossier, please email me directly: rob@13485cert.com. Medical Device Academy is developing a webinar series specifically for this purpose. You can also call me @ 802.258.1881.