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Changes to the way *In Vitro* Diagnostics medical devices are Regulated in Europe

The IVD Directive will soon be replaced by the IVD Regulation and this is a list of web links and documents that may be useful to address the regulations both now and in the future.

- The current IVD Directive:
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:331:0001:0037:EN:PDF
- Beginner's guide to the current IVD Directive:
  http://www.bsigroup.com/meddev/LocalFiles/en-GB/Technologies/BSI-md-ivd-diagnostic-directive-guide-brochure-UK-EN.pdf
- Summary of changes to the IVD Regulation (links to draft text and European Commission revision):
  http://www.bsigroup.com/en-GB/medical-devices/news-centre/enews/2012-enews/Revision-of-the-MDD-and-IVD-medical-devices-regulations
  http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision/index_en.htm
- Link to BSI free webinars:
  http://www.bsigroup.com/en-GB/medical-devices/resources/webinars/
- Current guidance to the IVD and Medical Device Directives:
  http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/index_en.htm
  This page also includes the current Common Technical Specifications (CTS) for IVDs, describing the testing requirements for high risk devices.
- Current harmonised standards list:
  http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices/index_en.htm
- Current guidance for medical devices and IVDs take the form of 'MEDDEV' documents:
  http://ec.europa.eu/growth/sectors/medical-devices/guidance/index_en.htm
- The Global Harmonisation Task Force (GHTF) documents. The International Medical Device Regulators Forum (IMDRF) replaces the GHTF but these documents are still relevant and archived on the IMDRF website:

    o Clinical Requirements
    http://www.imdrf.org/documents/doc-ghtf-sg5.asp

    o Technical Documentation format
    http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n063-2011-summary-technical-documentation-ivd-safety-conformity-110317.pdf

    o Risk management
    http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n15r8-risk-management-principles-qms-050520.pdf

    o Process validation
    http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n99-10-2004-qms-process-guidance-04010.pdf

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