

Provided below are several Web sites that may be of interest.

Recast of the Medical Devices Directives (comments due by July 2, 2008):

http://ec.europa.eu/enterprise/medical_devices/consult_recast_2008_en.htm

Consolidated version of the Medical Devices Directive MDD 93/42/EEC, incorporating modifications from Directive 2007/47/EC (note, footnote M5):

http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/cons_vers_93-42-eec.pdf

(Directive 2007/47/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:01:EN:HTML>.)

Guide to Implementation of the Directives Based on New Approach and Global Approach "Blue Guide" "Vade Macum" :

<http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm>

http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf

Guidances, MEDDEVs (MEDDEV 2.12.1 Rev. 5 and electronic Incident Report Form and FSCA Form):

http://ec.europa.eu/enterprise/medical_devices/meddev/meddev_index_en.htm

EU Commission Interpretative Documents (Medical Device and Machinery, Medical Device and PPE, OBL PBL):

http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/interpretative_documents_en.htm.

MDEG Borderline and Classification (Manual Ver 1.1 and 1.0):

http://ec.europa.eu/enterprise/medical_devices/borderline_classification_en.htm

GHTF Guidance document titled Clinical Evaluation

http://www.ghrf.org/documents/sg5/sg5_n2r8_2007final.pdf

NANDO Web site

<http://ec.europa.eu/enterprise/newapproach/nando/>

<http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.main> (searching by Directive)