List of the Italian and International laws and norms for clinical studies


3. [Directive 93/42 of CEE Council 14 of June 1993 concerning Medical Devices] (Italian),


5. [D.L. of 20/02/2007. News modalities for fulfillments planned into art. 13 of D.L. 24 of February 1997 n° 46 and following modifications and for active implantable Medical Devices registration as well as for inscription into the Medical Devices Registry] (Italian).

6. [D.L. of 21/12/2009 of Italian Ministry of Health. News modalities for fulfillments planned for active implantable Medical Devices registration as well as for inscription into the Medical Devices Registry] (Italian).


8. [MEDDEV 2.12-1 Revision 6 Guidelines concerning Medical Devices technical-vigilance] (Italian).


10. UNI CEI ISO 14971:2009 Medical Devices: Application of risk management to medical devices,


17. [Note of Italian Ministry of Health DGFDM. VI/6821/P-I.S.i.m.2 of 26 of February 2007. Administrative procedures concerning clinical investigations management involving Medical Devices with CE Mark] (Italian).

18. [D.L. of Italian Ministry of Health 17 of December 2004. General prescriptions and conditions, concerning drugs clinical investigations execution, referring to those oriented to improve clinical practice, as a part of health care] (Italian).


   Part 1: General requirements.