

Certification Approach	MDD 93/42/EEC/MDD2007/47/EEC AMEDING ANNEXVII
Standard	EN ISO 14971:2009 Medical Devices - Application of Risk Management to Medical Devices
	EN980:2008 Symbols for use in the labeling of medical devices
	EN ISO 10993-1:2009/AC2010 Biological evaluation of medical devices-Evaluation and testing
	EN ISO 10993-5:2009 Biological evaluation of medical devices-Tests for in vitro cytotoxicity
	ISO 10993-10:2002 AMD 2006 Biological evaluation of medical devices -Tests for irritation and delayed-type hypersensitivity
	EN 1041:2008 Information supplied by the manufacturer of medical devices