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Introduction to CE Marking

Course Description	This course help you make informed decisions with regard to meeting the requirements of the EU Medical Devices Directives. On completion of training, participants will be able to identify the steps required to reduce the risks and uncertainty in the EU regulatory process and thus bring products to the EU market more quickly.
Learning Objectives	Upon completion of this training, delegates will be able to: • Explain the European CE marking approach with respect to medical devices, active implantables and IVDs, including borderlines with other products, as covered by the three Council Directives (MDD, AIMDD, IVDD) and the underlying Commission Directives such as the animal tissue directive and blood derivative directives. • Explain the significance of the EU risk classification criteria for medical devices in determining the conformity assessment routes and quality assurance requirements for the various risk classes, as well as the routes to compliance for borderline products that include pharmaceuticals, human derivatives and/or engineered tissues. • Describe the role of the essential requirements as the basis for CE marking, including the use of standards. • Describe the role of clinical data and risk management. • Identify the necessary steps required for post market surveillance and for reporting adverse incidents under the vigilance system. • Identify technical documentation requirements
Intended Audience	• Senior management • Regulatory, quality, design, development, manufacturing, marketing managers and personnel. • Organizations preparing 'own branding' or 'private labelling' of devices
Course Duration	1 day.
Prerequisites	There are no formal prerequisites for this course but participants will benefit from a basic knowledge of medical device use or manufacture.