http://www.emergogroup.com/ce-marking-process-chart

## Determine which Directive applies to your device: Medical Devices Directive – 93/42/EEC In-Vitro Diagnostic Device Directive – 98/79/EC Active Implantable Medical Device Directive – 90/385/EEC Need to DETERMINE CLASSIFICATION of your device. This will determine which compliance steps you must follow. See Annex 9 (MDD) or Annex 2\* (IVDD). All Active Implantables are Class III. Sterile or Class IIb Class Class IIa Class III Measuring Implement a QUALITY MANAGEMENT SYSTEM (QMS), most commonly achieved using the ISO 13485\*\* Standard. Prepare a TECHNICAL FILE which provides detailed information intended to demonstrate compliance with the health and safety requirements stipulated in the Directive. Your QMS and Technical File must be audited by a NOTIFIED BODY to ensure you meet the requirements of the Directive. You must appoint an AUTHORIZED REPRESENTATIVE (EC REP) with a physical office in Europe. They must be identified on your labeling and qualified to handle regulatory matters. After successfully passing your registration audit and Technical File review, your Notified Body will issue a CE CERTIFICATE. Follow up audits will be required. ALL Class 1 medical devices must be registered with the COMPETENT AUTHORITY in the country where your EC REP is based. IVDs must be registered in every

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European country where sold. Class IIa, IIb and III\*\*\* devices do not require registration except in Italy