CE Marking

CE Marking is a legal requirement for medical devices intended for sale in Europe.
There are three European CE marking Directives that specifically apply to medical devices manufacturers:

1. The Medical Devices Directive (MDD) applies to all general medical devices not covered by the Active Implantable Medical Devices Directive or the In Vitro Diagnostics Directive.
2. The Active Implantable Medical Devices Directive (AIMDD) applies to all active devices and related accessories intended to be permanently implanted in humans.
3. The In Vitro Diagnostics Directive (IVDD) applies to all devices and kits used away from the patient to make a diagnosis of patient medical conditions (IVD are the analysis of medical samples, such as blood, tissues, or urine, that are taken from patients or healthy individuals).

Most of medical equipments are under MDD, directive 93/42/EEC, updated by 2007/47/EEC and are classified as below:

Class I ► producers/suppliers must prepare technical documentation and after having obtained full quality system registration, are entitled to self-declare (Declaration of Conformity) their compliance with CE. The elements that should be included in the Declaration of Conformity are:

- *Name of the device, including model number and trade name.*
- *Manufacturer/Supplier name and address.*
- *Name of company quality management representative.*
- *Conformity assessment route to compliance.*
- *Standards that have been applied.*
- *Name and signature of a senior management representative and date signed.*

Class IIa/b ► producers must implement a QUALITY MANAGEMENT SYSTEM (QMS) most commonly achieved using ISO 13485* standard; prepare a technical file with detailed information demonstrating compliance with health and safety requirements of directive 93/42/EEC, 2007/47/EEC and submit all to a Notified Body. After this, the Notified Body will issue a CE CERTIFICATE reporting the Notified Body identifying number.

Class III ► No items sold by Gima

In Vitro Diagnostics Directive (IVDD) are under directive 98/79/EC and require a Notified Body CE Certificate

93/42/EEC, 2007/47/EEC and 98/79/EC CE CONFORMITY:

CLASS I 93/42/EEC	CLASS II 93/42/EEC	CLASS III 93/42/EEC	IN VITRO	98/79/EC
Most of Gima products	Some Gima products	No products sold by Gima	Self test	Professional test
Self declaration	Notified Body CE Certificate	Notified Body CE Certificate	Notified Body CE Certificate	Self declaration

***ISO 13485** is an ISO standard, published in 2003, that represents the requirements for a comprehensive management system for the design and manufacture of medical devices.