Basic Requirements for Marketing of Medical Devices

Medical devices must generally bear a CE mark in order to be first placed on the market in the European Economic Area (EEA). The medical device bearing the CE mark must fulfil the essential requirements of the medical device legislation with regard to safety, performance and health protection and this must be documented in writing by way of a conformity assessment. Transitory periods still apply for medical devices with stable blood components (plasma derivatives).

Medical devices subject to Council Directive 93/42/EEC are divided into 4 (risk) classes: I, IIA, IIB and III. The rules for classification are listed in Annex IX of the Council Directive. The EU Commission has provided detailed explanations and examples for classifications in Guideline MEDDEV 2.4/1. You will find these guidelines on the EU Commission’s website (http://ec.europa.eu/enterprise/medical_devices/meddev/). If there is a difference of opinion between a manufacturer and a notified body as to the correct classification of a medical device, the notified body is to submit the matter to its competent authority for decision (§ 13 Law on Medical Devices – MPG). Aside from this, the binding decision on classification as well as for demarcation from other products is made by the health authority of the respective Federal State competent for the domicile of the manufacturer or its authorised representative. If the notified body or the person(s) responsible for first marketing are based in another country of the EEA, the decision by the competent authority of that country is applicable. In-vitro diagnostic medical devices are also divided into different "risk classes" (cf. Article 9 of Council Directive 98/79/EC); active implantable medical devices in accordance with Council Directive 90/385/EEC are not divided into different risk classes.

Fulfilment of essential and other legal requirements is determined in a formal conformity assessment procedure (cf. Ordinance on Medical Devices (Medizinprodukte-Verordnung) - MPV). Depending on the class of product, conformity can be proven by the manufacturer or with the involvement of a notified body. Such intervention is necessary for all active implants in accordance with Council Directive 90/385/EEC, for in-vitro diagnostic medical devices in accordance with Annex II of Council Directive 98/79/EC or for self-administration, as well as for other medical devices of classes III, IIB, or IIA and class I products which are placed on the market in a sterile condition or which have a measuring function.

A list of notified bodies for the European Economic Area can be found on the DIMDI's website (Deutsches Institut für Medizinische Dokumentation und Information, German Institute for Medical Documentation and Information, www.dimdi.de) under 'Medical Devices' > 'Addresses' > 'Notified Bodies'.

For proof of compliance with the legal requirements, the manufacturer can refer to harmonised standards and coequal monographs of the European Pharmacopoeia within the conformity assessment procedure. Harmonised standards in accordance with the medical device legislation are technical documents for concretisation of legal requirements. Application of these standards is voluntary; the manufacturer is free to prove compliance with the legal requirements in a different manner. However, adherence to a harmonised standard leads to the assumption of conformity. Common Technical Specifications (CTS) are of importance for the evaluation of critical in-vitro diagnostic medical devices. Adherence to the CTS leads to the assumption of conformity, however, they are de facto binding.

You will find further information on special requirements for marketing of medical devices bearing a CE mark in Germany (including further links on medical device legislation) in our info sheet 2.
The texts of the most important legal provisions (e.g. the MPG) and subordinated ordinances are published on the website of the Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) in subdirectory 'Gesetze und Verordnungen' (www.bmg.bund.de), on the DIMDI's website (Link > 'Medizinprodukte' > 'MP-Recht') as well as on the BfArM's website (www.bfarm.de) in the subdirectory 'Medizinprodukte'. Furthermore, there are other associations that could possibly give you further useful information (e.g. German Medical Technology Association (Bundesverband Medizintechnologie e.V., BVMed), Association of German Dental Manufacturers (Verband der Deutschen Dental-Industrie e.V., VDDI), 'Fachverband Elektromedizinische Technik im ZVEI' (association for electromedical engineering at the ZVEI), 'Verband der Diagnostica-Industrie e.V.' (VDGH) (association of the diagnostics industry), German Industrial Association for Optical, Medical and Mechatronical Technologies Inc. (Deutscher Industrieverband für optische, medizinische und mechatronische Technologien e.V., SPECTARIS). Also, several organisers offer seminars; possibly this information can be obtained from the homepages of the respective associations.