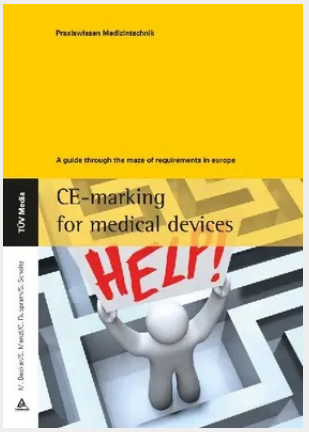
Becker / Menzel / Rupprath

CE-Marking



Medical devices are widely used – from prevention and diagnostics to treatment and rehabilitation. They are indispensable for the health sector, and do represent an important economic factor. Efficacy and safety of a product is of key importance for patients and users. CE-marking has to be affixed on all medical devices in Europe and is the visible feature of conformity of the medical device with essential legal requirements. CE-marking therefore is one of the most important objectives for manufacturers that want to distribute medical devices in Europe. The authors are working in the medical devices industry for many years. With their expertise they provide a competent but also practice-oriented overview of the European and national requirements for medical devices. This book is meant to be a workbook including exercises to deepen the knowledge on the CE-marking process for medical devices.

The development of medical technology in the last years of the 20th century has been very dynamic. Synthetic single-use products, artificial joint replacements, pacemaker technologies or minimal-invasive procedures result in a high standard of medical care. But despite of the huge progress in this field, we are presumably only at the beginning of a medical technology revolution.The 1st version of the German Medizinproduktegesetz (MPG, Medical Devices Act) came into effect on January 1, 1995. It represents the national implementation of the European directives 90/385/EEC for active implantable medical device, 93/42/EEC for medical devices and 98/79/EEC for in vitro diagnostic devices.With the implementation of this act in the EU internal market, the free movement of medical devices was established. Medical devices that are marketable in one member state of the EU are also marketable in the other EU countries. Manufacturers of medical devices can therefore place their products on the whole EU market.The CE-mark on the products is the proof of complying with the essential requirements. The Medical Devices Act guarantees the efficacy and safety of the medical device because the product has to undergo comprehensive control procedures during the design and manufacturing process. The CE-mark is a cachet for quality and efficacy. After the market access, the authorities take care of the safety for users and consumers via definition of essential requirements.This book presents the major aspects of the Medical Devices Act and the European directives. Moreover, the responsibilities and duties of a medical device manufacturer are explained as well as the product classifications and what the manufacturer has to keep in mind when designing and producing medical devices that comply with the legal requirements.A lot of physicians implant medical devices without being aware of the highly complex registration landscape. Especially in clinical research, the regulations regarding the use of medical devices should be known. The requirements of the ethics committee and of the legal departments of hospitals are getting more complex and therefore especially the scientist should get acquainted with this topic.

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