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The book discusses the legal and technical requirements for manufacturers, designers and testers of electromedical devices. It describes which obstacles must be overcome to introduce a medical device on the European market, but also informs readers as to pitfalls and opportunities, and in which way safety can be achieved and product liability

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Safety of electromedical devices Law Risks Opportunities

The book deals with legal and technical requirements for manufacturers, designers and testers of electromedical devices. It describes which legal obstacles must be overcome to place a medical

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It explains how the newly required risk management process, which comprises risk analysis, risk assessment, risk management and risk control, can be implemented. As a final essential consideration, the book describes which safety requirements are to be met and how they can be satisfied and tested.

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Safety of Electromedical Devices Law Risks

Free Preview Reviews the legal and technical requirements for manufacturers, designers and testers of electromedical devices Discusses risk analysis, risk assessment, risk management and risk control

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As a general rule, it is considered sufficient if electromedical devices meet those standards which were in force when they were put on the market. It is not mandatory to update devices already in use to meet actual standards. Therefore, for safety assessment of older devices it is helpful to know the historical development of medical safety standards.

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