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Safety of Electromedical Devices Law Risks

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 limited. It explains how the newly required risk

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Safety of Electromedical Devices Law Risks

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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AS 3200 1986 Approval and test specification

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Safety of piped medical gases and electromedical equipment

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Safety Testing of Medical Devices IEC 62353 Explained

In particular, IEC 62353 defines a series of test requirements and associated pass/fail limits that are designed to ensure the in-service safety of electromedical devices and systems. The standard contains tables with allowable values relating to different editions of IEC 60601-1 and includes general requirements and further clauses for special types of medical electrical equipment and systems.

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