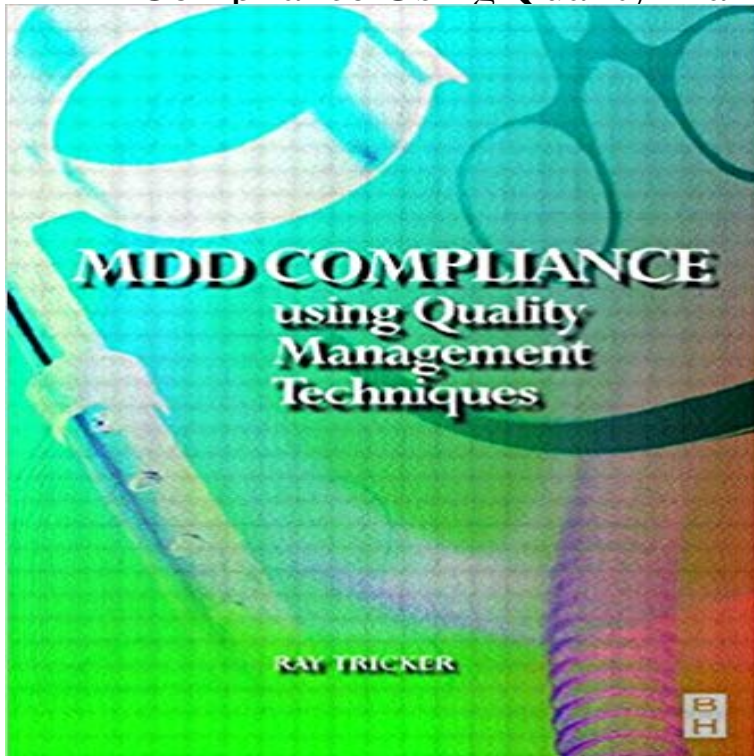


## MDD Compliance Using Quality Management Techniques



The Medical Devices Directive (MDD) is an all-encompassing document legislating for the manufacture of any medical device or material used either temporarily or permanently on or in the human body. To achieve its main objectives the MDD requires the manufacturer of all products covered by the Directive to possess a fully auditable Quality Management System consisting of Quality Policies, Quality Procedures and Work Instructions, based on the ISO 9000 standard. The book is based on the sound principles of ISO 9000 and will guide to the reader, if required, to eventually set up an ISO 9000 fully compliant system. MDD-Compliance using Quality Management Techniques consists of the following:\*

- \* A brief guide to the Medical Devices Directive - explaining the main requirements of the directive, translating legal Eurospeak into everyday language\*
- \* An overview of ISO 9000 and how the MDD links in with these international requirements.\*
- \* A Quality Manual - will provide a template for a complete Quality Management System that can be used by any product being produced under the requirements of the MDD\*
- \* CD ROM containing a software copy of the Quality Manual \*
- \* A User manual consisting of clear instructions and flow charts on how to set up and use the Quality Management System described in the Quality Manual

Easy to follow guide to MDD  
Written in clear, no nonsense format  
Quality manual will provide template for any product being produced under MDD

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