ISO 14971:2000, Medical devices -- Application of risk management to medical devices

ISO TC 210

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This International Standard specifies a procedure by which a manufacturer can identify the hazards associated with medical devices and their accessories, including in vitro diagnostic medical devices, estimate and evaluate the risks, control these risks and monitor the effectiveness of the control.The requirements of this International Standard are applicable to all stages of the life cycle of a medical device.This International Standard does not apply to clinical judgements relating to the use of a medical device.It does not specify acceptable risk levels.This International Standard does not require that the manufacturer has a formal quality system in place. However, risk management can be an integral part of a quality system (see, for example, Table G.1).

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