ISO 14971:2007, Medical devices - Application of risk management to medical devices

By ISO/TC 210

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ISO 14971:2007 specifies a process for a manufacturer to identify the hazards associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of ISO 14971:2007 are applicable to all stages of the life-cycle of a medical device.

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