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ISO - IEC/TR 80002-3:2014 - Medical device software - Part ...

IEC/TR 80002-1, Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software [8] National Institute of Standards and Technology (NIST) Special Publication 500-234, Reference Information for the Software Verification and Validation Process , Dolores R.

Wallace, Laura M. Ippolito, Barbara Cuthill, March ...

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Abstract IEC TR 80001-2-8:2016, which is a Technical Report, provides guidance to Health Delivery Organizations (HDOs) and Medical Device Manufacturers (MDMs) for the application of the framework outlined in IEC TR 80001-2-2.

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The IEC/TR 80002-1 and ISO 14971 Medical Devices Software Package specifies the process of identifying, controlling and monitoring risk and hazards associated with medical device software.

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