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IEC 60601-1: Changes From 2nd To 3rd EditionA Risk Management Process According To ISO 14971 Shall Be Performed. This Means That Certification To IEC 60601-1 Is Not Possible Without Compliance With ISO 14971. However, Certification To ISO 14971 Is Not Required. A Certificate For ISO 14971 Is Certainly A Useful Asset, But It Does Not Exempt The Safety Test Apr 2th, 2024IEC 60601-1: Changes From 2nd To 3rd Edition - ETL SEMKOThe ETL Mark Will Not Be Withdrawn For Several Years, And Only If The Device Is Modified. You May Start Using The 3rd Edition Now For The ETL Mark. Since Both The FDA And Health Canada Now Recognise Th Mar 7th, 2024IEC 60601-1: The New Philosophy Of The 3rd EditionIEC 60601-1 Is Intended

To Serve As A Tool In The Risk Management Process. To That End, Clause 4.2 Specifies: A Risk Management Process According To ISO 14971 Shall Be Performed. This Means That Certification To IEC 60601-1 Is Not Possible Without Compliance WithFile Size: 744KBPage Count: 22 Mar 2th, 2024.

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