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Chapter 1 : IEC | IEC Webstore

IEC Third Edition Amendment 1 (Ed.) What you need to know. For manufacturers of medical electrical equipment and systems, IEC Edition (or IEC +AMD) represents a significant departure from Edition of the standard.

If you are in the process of developing a new electronic medical device or are currently revising an existing device, you need to pay close attention. Risk Management Usability Software One key aspect of each of these areas is that they are full lifecycle, meaning they are not one-time or even short term events like EMC or Electrical Safety testing. They are aspects of the product design that continue through the lifecycle of the product. And that can be a long time at least we hope so. A second key aspect of each of these areas is that they cannot be confirmed through testing and inspection of the product, as was possible with many aspects of the 2nd edition. Rather, each of these areas represents a process which needs to be in place and producing results that demonstrate conformance to the Standards. Put in place processes within your product development process that address each of these areas throughout the product lifecycle. In the 2nd edition of the standard, companies could confirm compliance through inspection and testing of the product. Not so with the latest standard. Each of these new requirements needs to be incorporated directly into your design, manufacturing, and post-production processes. These processes are necessary in order to produce objective evidence in order to demonstrate compliance with the Standard. The 3rd Edition addresses these 3 areas in two ways: Directly within the 3rd Edition itself; or By requiring conformance to a Collateral Standard With respect to these 3 areas, the applicable Collateral Standards are: ISO current latest Edition Usability: For now it is important to understand that these 3 are not separate areas in and of themselves. Rather, they are so interdependent that one needs to think in terms of implementing processes that integrate all 3 into your ongoing product development process. The key backbone to the Standard is full lifecycle Risk Management. Implement a Risk Management process that starts at product concept and continues throughout post-production monitoring. Implement a Usability Engineering process that starts at product concept and continues throughout post-production monitoring, and Reduces Usability risks to as low as is reasonably practicable Identifies, evaluates and implements Usability improvements that make the product better Implement a Software Engineering process that starts at product concept and continues throughout post-production monitoring, and Reduces Software-related risks to as low as is reasonably practicable Identifies, evaluates and implements Software improvements that make the product better This can be a daunting and expensive task. The experts at BDA are here to help. Please call us at to schedule your free consultation. Subscribe Now Importing Medical Devices? Our partner provides post-production support services primarily to Medical Devices companies wanting to outsource Call-handling and portions of Complaint Handling, Medical Device Reporting, U. Learn More Device Tips Emails Be one of the first to know when we publish a new device tip by getting them sent straight to your inbox.

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Chapter 2 : Medical Device FDA Requirements and IEC Information

IEC 3rd Edition Standard IEC is a widely accepted series of international standards for the basic safety and essential performance of medical electrical equipment. Your new and existing medical devices must demonstrate compliance with the latest revision of IEC

General requirements for basic safety and essential performance - gives general requirements of the series of standards. This standard does not assure effectiveness of a medical device. Revisions[edit] In , the third edition of IEC was published. It was the result of a comprehensive review of the second edition dating from Some key changes are: IEC must now be incorporated into the design and verification of a wide range of home use and point of care medical devices along with other applicable standards in the IEC 3rd edition series. The North American agencies will only require these standards for new device submissions, while the EU will take the more severe approach of requiring all applicable devices being placed on the market to consider the home healthcare standard. Collateral standards numbered X define the requirements for certain aspects of safety and performance, e. Particular standards numbered X define the requirements for specific products or specific measurements built into products, e. A list of the collateral and particular standards currently in force follows: General requirements for basic safety and essential performance - Collateral Standard: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC Medical electrical equipment - Part Requirements for environmentally conscious design IEC Medical electrical equipment - Part Requirements for the development of physiologic closed-loop controllers IEC Medical electrical equipment - Part Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment IEC Medical electrical equipment - Part Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of cardiac defibrillators IEC Medical electrical equipment â€" Part Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of microwave therapy equipment IEC Medical electrical equipment - Part Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of nerve and muscle stimulators IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC Medical electrical equipment - Part Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of endoscopic equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of infant incubators IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of infant transport incubators IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of infant radiant warmers IEC Medical electrical equipment - Part Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment IEC Medical electrical equipment - Part

Particular requirements for the basic safety and essential performance of infusion pumps and controllers IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of electrocardiographs IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of electroencephalographs IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC Medical electrical equipment - Part Particular requirements for basic safety and essential performance of peritoneal dialysis equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC Medical electrical equipment - Part Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammomagraphic stereotactic devices IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of operating tables IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of infant phototherapy equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of medical beds IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound HITU equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment IEC Medical electrical equipment - Part Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems IEC Electrical medical equipment - Part Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment For example, IEC for Environmentally Conscious Design of Medical Electrical Equipment published July is a collateral standard to IEC and has been developed drawing on extensive practical experience at Philips Medical Systems and Siemens Medical Solutions. The standard also requires that the manufacturer provide information to the user on how to use the product in the most environmentally sensitive way. The USA , Canada , Japan , Australia and New Zealand have not yet set transition dates for their national versions of this latest edition , but the national versions published to date do contain the requirement to also conform with IEC However, the

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European version EN In the United States, nursing facilities are considered to be environments providing professional healthcare. Although In Vitro Diagnostic devices such as blood glucose meters are being used by patients at home, the standard does not apply, as these devices remain under the jurisdiction of the more lenient IEC series[citation needed]. Critics[edit] The certification process has been criticized for its complexity, cost, and the business risk it raises. This has been more particularly a concern during the transition to the third edition due to the indefinite adoption schedule of the new revision.

Chapter 3 : IEC - Wikipedia

EN 3rd Edition version contains several hundred changes from version , some of which are significant EN 3rd Edition version has a cessation date of December , but devices for which Annex ZZ of the standard is applicable face a compliance date of 1 January

Chapter 4 : IEC 3rd Edition, Part 1 Differences | Bob Duffy Associates

IEC () must now be incorporated into the design and verification of a wide range of home use and point of care medical devices along with other applicable standards in the IEC 3rd edition series.

Chapter 5 : Electrical | Industries | UL

More details on IEC 3rd Edition Differences. As mentioned in our Device Tip, the 3rd Edition of IEC is now in effect. Issued in , European and Canadian companies were given until June 1, to comply with the new standard (US companies have until 6/30/13 to comply).

Chapter 6 : IEC +AMD CSV | IEC Webstore

, 3rd Edition, Medical electrical equipment, Part 1 ANSI/AAMI ES, Medical electrical equipmentâ€"Part 1: General requirements for basic safety and essential performance is the third edition of the standard that covers any medical device that requires an electrical outlet or a battery.

Chapter 7 : IEC 3rd Edition Standard

The 3rd Edition of IEC represents a shift in philosophy from the 2nd Edition, including a greater emphasis on risk management and essential performance.

Chapter 8 : UL Knowledge Solutions - Designing for Compliance to IEC 3rd Edition eLearning

As new jurisdictions adopt the third edition, the evolution of a global strategy for third edition must keep pace with the changing regulatory landscape. Indeed, acceptance of third edition is coming and though it has taken what seems to be a long time to reach the current limited recognition (the standard has been published.

Chapter 9 : IEC Download Free Compliance Documents

3rd edition's "two MOOP" and "one MOPP" requirements, and 2nd edition Type CF not only requires an IEC qualified supply, but must ensure an additional isolation barrier between the supply and the part that touches the patient.