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iec 60601 is a series of technical standards for the safety and essential performance of medical electrical equipment published by the international electrotechnical commission first published in 1977 and regularly updated and restructured as of 2011 it consists of a general standard about 10 collateral standards and about 80 particular this standard specifies the basic safety and essential performance of medical electrical equipment and systems used in the home healthcare environment it applies to equipment and systems for lay operators or trained healthcare personnel and covers test methods humidity control and amendments steris ast offers technical support and testing services for medical electrical equipment according to iec 60601 and iec 61010 standards learn about the difference between the two standards the test methods and the product examples learn how to classify your medical electrical equipment mee according to iec 60601 1 standard which covers protection against electric shock water and particulate ingress and sterilization methods find definitions examples and references for each classification this guidance explains how the fda recognizes consensus standards for basic safety and essential performance of medical electrical equipment systems and laboratory equipment under the asca pilot program it also provides information on premarket submission contents accreditation and assessment of testing laboratories and paperwork reduction iec 60601 1 and its collateral standard iec 60601 1 2 are the primary documents that govern requirements for power supplies in medical devices for those integrating medical grade power supplies into their designs cui offers multiple iec compliant offerings that can streamline the design process

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this standard specifies the basic safety and essential performance of medical electrical equipment and systems used in the home healthcare environment it applies to equipment and systems for lay operators or trained healthcare personnel and covers test methods humidity control and amendments

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## <u>iec 60601 medical electrical equipment classification</u> <u>faqs</u>

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