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Compliance with Medical Standards IEC 62304, ISO 14971, IEC 60601, FDA Title 21 CFR

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International Standard IEC 60601-2-33 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice. This second edition cancels and replaces the first edition published in 1995 and constitutes a technical revision.

~~INTERNATIONAL IEC STANDARD 60601-2-33~~

This third edition of IEC 60601-2-33 is based on the second amendment to Edition 2. It has also been adapted to the third edition of IEC 60601-1 (2005), with technical modifications being introduced where appropriate. The contents of the corrigenda of March 2012 and February 2016 have been included in this copy.

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IEC 60601-2-33, 3.2 Edition, June 2015 - Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MR EQUIPMENT and MR SYSTEMS, hereafter referred to also as ME EQUIPMENT.

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The general standard IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - gives general requirements of the series of standards. 60601 is a widely accepted benchmark for medical electrical equipment and compliance with IEC60601-1 has become a requirement for the commercialisation of electrical medical equipment in many countries.

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~~IEC 60601-2-23 Ed. 3.0 b:2011~~

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