

EMC: Recognized Standards

On August 6, 2013, the FDA issued a federal register notice Modifications to the List of Recognized Standards, Recognition List Number: 032 (<http://www.gpo.gov/fdsys/pkg/FR-2013-08-06/pdf/2013-19020.pdf>).¹ that recognizes voluntary consensus standards to help support and strengthen the interoperability and cybersecurity of networked and connected medical devices.

- **IEC 60601-1-2**
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/SimpleSearch.cfm?db=STD&id=14761>), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).
- **AAMI / ANSI / IEC 60601-1-2**
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/SimpleSearch.cfm?db=STD&id=14760>), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- **ANSI / RESNA WC/Vol. 2-1998**
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/SimpleSearch.cfm?db=STD&id=8164>), Section 21, Requirements and test methods for electromagnetic compatibility of powered wheelchairs and motorized scooters.
- **ANSI C63:19:2001**
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/SimpleSearch.cfm?db=STD&id=8507>), Methods of Measurement of Compatibility between Wireless Communication Devices and Hearing Aids