This addendum provides updates to the Selenia® Dimensions® and 3Dimensions™ compliance statements. The addendum lists relevant compliance statements.

Place this addendum with your manual for future reference.

1.1 Compliance

This section describes the mammography system compliance requirements and the responsibilities of the manufacturer.

1.1.1 Compliance Statements

The manufacturer states this device is made to meet the following requirements:

Medical – Applied electromagnetic radiation equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1 (2005)/A1: 2012 C1:2009/(R)2012 and A2:2010/(R)2012 and CAN/CSA-C22.2 No. 60601-1 (2008)

- CAN/CSA - ISO 13485-03 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes (Adopted ISO 13485:2003 second edition, 2003-07-15)
- Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance
- EN 1041 2008: Information supplied by the manufacturer of Medical Devices
- EN ISO 14971 2012: Medical Devices – Application of Risk Management to Medical Devices
- EN ISO 10993-1/AC 2009/2010: Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
- EN ISO 15223-1 2016: Medical Devices – Symbols to be used with Medical Device Labels, Labelling, and Information to be Supplied – Part 1: General Requirements
- EN 60601-1: 2006 + CORR: 2010 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- ETSI EN 300 330-1: V2.1.1,—Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz
- ETSI EN 301 489-1: V2.2.0,—Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services
- FCC, 47 CFR Part 15, Subpart C, Section 15.225: 2009
- FDA, 21 CFR [Parts 820, 900 and 1020]
- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007): Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

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- IEC 60601-1-2 Ed. 4th 0:2014 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-1-3 Ed. 2.0:2008: Medical Electrical Equipment – Part 1-3: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment
- IEC 60601-2-28 Ed. 2.0:2010 Medical Electrical Equipment - Part 2-28: Particular Requirements for the Basic Safety and Essential Performance of X-ray Tube Assemblies for Medical Devices
- IEC 60601-2-45 Ed. 3.0:2011: Medical Electrical Equipment – Part 2-45: Particular Requirements for Basic Safety and Essential Performance of Mammographic X-Ray Equipment and Mammographic Stereotactic Devices
- IEC 60601-1-6 2010 +A1 2013: Medical Device Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
- IEC 62304 2006: Medical Device Software – Software Life-cycle Processes
- IEC 62366 2015: Medical Devices – Part 1: Application of Usability Engineering to Medical Devices
- RSS-210: Issue 9, Annex B.6 Radio Standards Specification Low-power License-exempt Radiocommunication Devices: Category I Equipment

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