



EU DECLARATION OF CONFORMITY

Rauland, a Division of AMETEK Inc., declares that the Responder® 5000 Nurse Call System complies with the following standards to meet the essential requirements of the applicable directives.

Council Directive: 2014/35/EU - Electrical equipment designed for use within certain voltage limits – (LVD - Low Voltage Directive):

- IEC/EN 60950-1 Information Technology Equipment – Safety- Part 1: General Requirements (2nd Edition); A 1:2009 and EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011 + A2:2013 (which includes all European national differences)
- EN/IEC 60601-1: 2005 + CORR.1: 2006 + CORR.2: 2007 + AM1: 2012 (2nd Edition) Medical Electrical Equipment Part 1-1 – Collateral Standard: Safety Requirements for Medical Electrical Systems (Systems Standard)
- DIN EN 60601-1 (VDE 0750 Teil 1): 2013-12; EN 60601-1/A1:2013-10 IEC 60601-1 (ed.3); am1 (Medical Electrical Equipment Package - general requirements for basic safety and essential performance of medical electrical equipment and medical electrical systems)

Council Directive: 2014/30/EU - Electromagnetic Compatibility Directive:

- IEC 60950-1-2 (EMC) Medical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests + AC:2010 – IEC 60601-1-2: 2007 + INT1:2010 Standard Date: 2007
- EN 55022: Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement + AC:2011 – IEC CISPR 22:2008 Standard Date: 2010
- EN 55024: Information technology equipment – Immunity characteristics – Limits and methods of measurement – IEC CISPR 24:2010 Standard Date: 2010
- EN 61000-3-2: Electromagnetic compatibility (EMC) – Part 3-2: Limits-Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) + A1:2009+A2:2009 – IEC 61000-3-2:2005 + A1:2008 + A2:2009 Standard Date: 2006
- EN61000-3-3: Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment



with rated current $\leq 16A$ per phase and not subject to conditional connection – IEC 61000-3-3:2008 Standard Date: 2008

- EN 61000-4-2: Electromagnetic compatibility (EMC) – Part 4-2: Testing and Measurement Techniques – Electrostatic Discharge Immunity Test: 2009
- EN 61000-4-3: Electromagnetic compatibility (EMC) – Part 4-3: Testing and Measurement Techniques – Radio Frequency, Electromagnetic Field Immunity Test: 2006 + A1:2008 + A2:2010
- EN 61000-4-4: Electromagnetic compatibility (EMC) – Part 4-4: Testing and Measurement Techniques – Electrical Fast Transient/Burst Immunity Test: 2004 + A1:2010
- EN 61000-4-5: Electromagnetic compatibility (EMC) – Part 4-5: Testing and Measurement Techniques – Surge Immunity Test: 2006
- EN 61000-4-6: Electromagnetic compatibility (EMC) – Part 4-6: Testing and Measurement Techniques – Immunity to Conducted Disturbances, Induced by Radio Frequency Field: 2009
- EN 61000-4-8: Electromagnetic compatibility (EMC) – Part 4-8: Testing and Measurement Techniques – Power Frequency Magnetic Field Immunity Test: 2010
- EN 61000-4-11: Electromagnetic compatibility (EMC) – Part 4-11: Testing and Measurement Techniques – Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests: 2004

Council Directive: 2012/19/EU - Waste Electrical and Electronic Equipment Directive (WEEE Directive).

Council Directive: 2011/65/EU Article 7(b) - RoHS Recast Directive, Restriction of certain dangerous substances commonly used in electronic and electronic equipment.

The technical documentation to demonstrate compliance is maintained by Rauland, a Division of AMETEK in Mount Prospect and is available for inspection by the relevant authorities. Any modification of these devices not authorized by Rauland will invalidate this declaration.

The attention of the purchaser, assembler or user is drawn to the special precautions and limitations which are included in the Technical and User Manuals for the product and which are also available from Rauland upon request.

Sincerely,

Jim Senjanin 6/15/2017

Jim Senjanin
Director Quality Assurance/Regulatory Affairs
Rauland, a Division of AMETEK Inc.