Rauland-Borg and UL1069 & FDA Registered:

Built For Healthcare, Safety-Grade For Hospitals, and UL Certified.



"Rauland-Borg has an absolute commitment to the certifications that ensure life safety-grade reliability. Today, Rauland-Borg's products carry listing marks from UL, CUL, CSA, FCC and CE. Our products are unique in that they are registered as medical devices with the US Food & Drug Administration."

– Rauland-Borg Responder® Systems & Underwriters Laboratory 1069 (UL 1069)



ANSI/UL 1069 is the Standard for Hospital Signaling and Nurse Call Equipment. The Standard contains the necessary functional and reliability requirements for Nurse Call products certified by Underwriters Laboratories Inc. These requirements address all individual system components that make up a nurse call system intended to provide audible and visual communication between patients and healthcare personnel. The Standard also address miscellaneous signaling equipment employed in hospitals, including annunciation devices, and power supplies for nurse call systems, etc.

Compliance to the ANSI/UL 1069 Standard by Rauland-Borg is one of the conditions of coverage verified by Responder® Nurse Call Systems. Our products are rigorously tested and certified by UL in accordance with the Standard. As such, our Responder® Nurse Call Systems are intended to be installed in either general or critical care areas in accordance with the National Electrical Code, NFPA 70, and the Standard for Health Care Facilities, NFPA 99.

Rauland's Responder® Nurse Call Systems are also certified by UL to the Canadian standard CSA-C22.2 No 125-M1984 "Electromedical Equipment" category.

For more information about Underwriters Laboratory & UL 1069 Standard for Hospital Signaling & Nurse Call Equipment, please visit www.ul.com



Rauland-Borg Responder® Systems U.S. Food and Drug Administration (FDA) Medical Device Classification

The Responder® Systems are considered medical devices by the US Food and Drug Agency (FDA), and are subject to federal regulation. Thus, Rauland-Borg is a registered medical device manufacturer with the US Food and Drug Agency (Registration Establishment # 1000227151).

Based upon FDA's device classification system, Rauland's Responder® product line has been classified under 21 CFR 890.3725 Powered Environmental Control System, a Class II medical device. Pursuant to the 1997 FDA Modernization Act, Rauland's Responder® product line is no longer subject to the 510(k) device submission requirement (Class II "exempt").

As a Class II exempt medical device, Rauland-Borg is required to comply with the Quality System Requirements (QSR's), the Medical Device Reporting requirements (MDR), and other provisions intended to provide our customers with even greater quality assurance and overall product safety.

For more information about the U.S. Food and Drug Administration (FDA) Medical Device Classification and to view Rauland's establishment and device listing, please visit: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

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