Norman Noble, Inc. Secures ISO 13485:2016 Recertification

Reinforcing Commitment to Medical Device Quality and Compliance

HIGHLAND HEIGHTS, OHIO – October 30, 2024 – Norman Noble, Inc., a global leader in the contract manufacturing of advanced medical implants and devices, announces the successful renewal of its Quality Management System (QMS) certification to the ISO 13485:2016 standard. This milestone comes after an extensive and thorough audit conducted by the British Standards Institute (BSI), a prestigious European Union Notified Body.

ISO 13485:2016 is an internationally esteemed quality standard specifically designed for the medical device sector. By securing this recertification, Norman Noble reaffirms its steadfast commitment to upholding the highest standards of product quality and regulatory compliance in the medical device industry. The company has maintained ISO 13485 certification since 2004, consistently demonstrating a proactive approach to meeting evolving regulatory requirements on both domestic and global fronts, including those set by the FDA, European MDR, and Brazil ANVISA.

This achievement not only fortifies Norman Noble's reputation as a trusted partner in the medical device manufacturing industry but also provides crucial support to its customers in navigating the complex regulatory landscape.

About Norman Noble, Inc.
Established over 75 years ago, Norman Noble, Inc. remains a family-owned and -operated company offering the most advanced processes for ultra-precision micromachining of medical implants. The company is known for its exceptional ability to produce nitinol-based implants and to achieve sub-miniature precision beyond the reach of most manufacturers. Norman Noble, Inc. is a supplier to most of the largest OEMs and well-known names in the medical device industry.

Norman Noble manufactures medical devices and implants to customer specifications in compliance with FDA regulations and ISO 13485. State-of-the-art processes include athermal laser machining, laser welding, Swiss turning and milling, conventional and wire EDM, high-speed 7-axis contour milling, electropolishing, nitinol shape setting, and clean room assembly and packaging. Rapid development prototyping services are available in separate and fully dedicated process development centers. FDA Registration #1531050. Virtual tour and more information: www.nnoble.com.

Media Inquiries:
Brian Hrouda, Director of Global Sales and Marketing
Norman Noble, Inc.
Tel: 216-761-5387 / Email: bhrouda@normannoble.net

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