Norman Noble, Inc.
Microprecision Medtech Manufacturing

Norman Noble, Inc. Adds Dedicated Support for EU MDR Regulated Customers

HIGHLAND HEIGHTS, OHIO – June 21, 2022 – Norman Noble, Inc., the world's leading contract manufacturer of next-generation medical implants, has recently added dedicated staff to its Quality team to support the critical needs of customers supplying the European market. Quality Assurance Resources provide support for meeting the new European Union Medical Device Regulation requirements, such as chemical reporting and conflict mineral reporting. This includes "Regulation (EU) 2017/745 on Medical Devices" which became effective on May 26, 2021.

"NNI recognizes the importance of efficient and accurate chemical content reporting to customers," said David Saletrik, Director of Quality Assurance at Norman Noble. "The NNI Quality Assurance Group has staff trained and assigned to respond to (EU) 2017/745 requests in addition to the related REACH, (EC 1907/2006), RoHS 3 Directive (2015/863), California Proposition 65 Act, and other related regulations."

Formal Documentation of Medical Device and Medical Device Component cleanliness has become increasingly critical to Norman Noble's customers' regulatory compliance and new product approval needs. In response, Noman Noble operates and maintains a final cleaning process validated in accordance with ASTM F3127-16 in addition to select customer product cleanliness requirements. The validation strategy defines a series of robust tests which incorporate various raw material types (stainless steel, titanium Nitinol, PEEK, etc.) and their resulting cleanliness after being exposed to processing material and chemicals.

Norman Noble Human Resources has also implemented a human rights and anti-human trafficking policy—a request that frequently comes from customers along with conflict minerals reporting. The policy applies to all persons employed by or engaged to provide services to Norman Noble, including, but not limited to, employees, temporary workers, consultants, suppliers, and business partners.

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.

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