



Norman Noble Clean Room Upgrade Meets ISO 14644 Class 7 Standards

Enables Clean Room Packaged Products to be Shipped Direct to Sterilization

HIGHLAND HEIGHTS, OHIO – May 10, 2021 – Norman Noble, Inc., a medical device contract manufacturer, today announced it has recently completed an upgrade to its Clean Room and attached Gowning Room to meet the ISO 14644 Class 7 requirements. Previously certified to ISO class 8, the new class 7 certification permits only 10% of the airborne particulate allowed under class 8. Testing is completed with a Light Scattering Airborne Particulate Counter (LSACP) sampling one cubic meter of air at a time. Samples are taken in 13 discrete locations within the Clean Room while it is in use.

“This improvement is intended to meet and exceed our customers’ needs for increasingly strict product cleanliness requirements” according to Dave Saletrik, NNI’s Director of Quality Assurance. The Clean Room is used for final assembly and packaging of finished medical devices and medical device components with strict cleanliness requirements. This is especially critical for customers who do no further down-stream cleaning of their products. It also allows NNI to ship finished, packaged medical devices direct to sterilization, saving our customers time and transportation costs. The ISO 14644 Class 7 requirements include strict requirements to control factors such as clothing, gloves and masks, regular cleaning and disinfection procedures, unidirectional airflow and regular testing for particulate and microbial contamination levels. NNI takes extra measures to assure product integrity by alternating through multiple types of disinfectants and maintaining a strict latex-free environment.

About Norman Noble, Inc.

Norman Noble, Inc., established 75 years ago, remains a family-owned and -operated company, offering the most advanced processes for ultra-precision micromachining. The company is known for its exceptional ability to micromachine nitinol implants and to achieve subminiature precision beyond the reach of most manufacturers. Norman Noble 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 regulation 21 CFR part 820 and ISO 13485:2016. State-of-the-art processes include laser machining and welding, Swiss turning and milling, conventional and wire EDM, high-speed seven-axis contour milling, nitinol shape setting, and clean room assembly and packaging. Rapid prototype services are available in separate and fully dedicated process development centers. For more information please visit www.nnoble.com.

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