

EnPak LLC Announces ISO 13485:2016 Certification

Milestone Reinforces EnPak's Commitment to Quality Standards

WARSAW, IN, UNITED STATES, April 3, 2025 /EINPresswire.com/ -- EnPak LLC, an established provider of logistics and operations services for the medical device industry, is proud to announce its quality system is now ISO 13485:2016 certified. This certification confirms that the company's quality management system complies with the latest regulatory standards for the medical device industry.

ISO 13485:2016 is a globally recognized standard for quality management systems, specifically tailored to organizations involved in the lifecycle of medical devices. Certification requires a successful third-party audit of the organization's quality system. Enpak's audit and Certificate of Registration were provided by Eagle Registrations Inc.

"Certification to ISO 13485:2016 underscores our dedication to providing exceptional services to our MedTech partners," said Marlene Mulero-Betances, President and CEO of EnPak LLC. "It validates our commitment to ensuring the highest standards of quality, compliance and reliability throughout the medical device supply chain."



Marlene Mulero-Betances, center, with the EnPak LLC team



In addition to ISO 13485:2016 certification, EnPak LLC is registered with the FDA and the quality management system meets FDA 21 CFR Part 820 requirements.

About EnPak LLC

Founded in 2011, EnPak LLC helps MedTech companies of all sizes bring their products to market by providing essential consulting, logistics services and operational support. With no minimum requirements, EnPak offers cost-effective solutions and quick turnaround times to keep businesses moving forward.

EnPak has partnered with [Ecoclean](#) to create an innovative center for cleaning and packaging services. Together, the companies will provide state-of-the-art solutions for pre-cleaning, final cleaning and contract cleaning services for medical device operations.

Located in Warsaw, Indiana—the “Orthopedic Capital of the World®”—EnPak is rooted in a community with significant global influence in technology and innovation. The company is dedicated to supporting medical device manufacturers by prioritizing quality and a people-first approach in everything it does.

For more information about EnPak’s services, please visit the company’s [website](#).

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