



For Immediate Release

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NICO Corporation Among Early Companies to Successfully Transition to New EU MDR Requirements for Class III Medical Devices

Monumental effort required to meet stricter clinical compliance standards compared to EU MDD

INDIANAPOLIS, IN (April 27, 2023) – [NICO Corporation](#), an Indianapolis-based pioneer and leader in minimally invasive neurosurgery, announced today it is among early companies to successfully complete transition to the new European Union (EU) Medical Device Regulation (MDR). This regulation is considered to be the most comprehensive and stringent medical device regulation in the world and allows NICO to continue providing its innovative, clinically proven Class 3 medical device products to patients across Europe.

Achieving EU MDR certification is a significant milestone for NICO that included a rigorous process demanding compliance with stricter requirements in quality management systems, manufacturing processes, product design, and clinical data monitoring.

“Our devices encompass the full range of EU classifications, including multiple EU class III products,” said Jay Dittman, Vice President of Operations at NICO. “The expectations under MDR have set a new standard for medical devices in Europe. Years of planning and preparation were required to handle raised expectations, numerous audits, simultaneous reviews, and challenges with notified body capacity. Our Quality, Regulatory and Engineering team achieved a monumental milestone for NICO.”

NICO's successful transition to the new regulation demonstrates its commitment to safety and quality in the design, manufacture and distribution of their products and positions the company for continued success in the global medical device market.

"This certification supports our determination to improve clinical outcomes through true minimally invasive neurosurgery that is safe and less traumatic for the patient and more efficient for the neurosurgeon," said Jim Pearson, president and CEO of NICO Corporation. "We continue to work toward advancing and expanding our product portfolio that offers a complete solution for minimally invasive neurosurgery, as well as enabling improved processing for oncology precision medicine using our novel method of tissue collection and biological preservation."

NICO is the first and only company in the world to develop and patent technologies to create an entirely new minimally invasive surgical market in neurosurgery for subcortical and skull base lesions. NICO technologies have been featured in more than [180 peer-reviewed publications](#) with over 550 unique authors from major academic centers. Data from these publications suggest improved clinical outcomes in Minimally Invasive Parafascicular Surgery (MIPS).

Learn about NICO technologies at NICOneuro.com; follow us on [LinkedIn](#) and [Twitter](#), view surgical and patient videos on [YouTube](#).

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