



X-Guide® Is The First Dental Surgical Navigation System To Receive EU MDR Certification

Global achievement signifies the Company's commitment to quality and safety, while paving the way to deliver continued innovation and growth for surgeons and patients

LANSDALE, PA. February 23, 2024 -- X-Nav Technologies, LLC announced that the X-Guide® Dynamic 3D Surgical Navigation System is the first of its kind to receive certification under the European Union Medical Device Regulation 2017/745, commonly referred to as EU MDR.

The EU MDR is one of the most rigorous medical device regulations in the world today, intended to ensure a higher standard of safety and quality in the development and manufacturing of medical devices distributed in the European market.

The regulation requires a thorough audit of a company's Technical Documentation, Clinical Evidence, and Quality Management System. The completion of this process certifies that the X-Guide System delivers the claimed clinical benefits for dental surgical procedures, including dental implant surgery and endodontic access.

"This certification reflects X-Nav's commitment to quality, safety, and performance that go into all products and processes," said Kimberly Chan, Director of Regulatory Affairs and Quality Assurance at X-Nav Technologies. "I am pleased to see our high standards rewarded with this distinction. We are honored to be a leader in our field and among the top medical device companies capable of meeting this regulation."

With EU MDR certification, X-Nav is in a unique position to support our European customers, partners, and patients with hardware, software and feature updates, as well as deliver future innovations that will drive value for our customers.

"I am proud of the in-house X-Nav team for their dedication and collective efforts in achieving this milestone for the business," stated Edward Marandola, President and CEO of X-Nav Technologies. "It reflects our commitment as a global leader in delivering high-quality and innovative medical devices. This sets us up to deliver our roadmap of future surgical solutions."

The EU MDR certification is a notable addition to the existing portfolio of X-Nav's quality and regulatory accomplishments. You can learn more about X-Nav's commitment to quality programs by visiting www.X-NavTech.com/quality-regulation.



X-Guide is the industry-leading surgical navigation system used by dentists and clinicians around the world to deliver more accurate and less invasive dental surgical procedures with remarkable precision. From single implant placement to full arch reconstruction, the X-Guide delivers precision, control, and confidence during surgery.

The X-Guide Surgical Navigation System is available in 23 languages and 50+ countries, holds 31 trademarks and 50+ patents, and is used by over 50 universities around the world.

About X-Nav Technologies

At X-Nav Technologies, we create innovative image-guided surgical navigation and robotic-assisted products to drive safer, more accurate, and minimally-invasive surgical procedures for dental patients, while improving the surgical experience for the doctor. We innovate to deliver solutions that we believe will help clinicians practice better dentistry. X-Nav Technologies, LLC is a privately-held, independent company whose devices have a global footprint. www.X-NavTech.com

