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Tecomet earns MDR Certification from the European Medical Device Regulation

Woburn, MA (June 12, 2025) – Tecomet Inc. (or the"Company"), a leading contract manufacturer of orthopedic implants, instruments, and sterilization trays, announced today that its Kenosha, WI, location achieved certification to the European Union Medical Device Regulation (EU MDR 2017/745) for all Tecomet-designed products. The EU MDR represents one of the most rigorous regulatory frameworks globally that govern the production and distribution of medical devices in Europe. Tecomet's successful transition from the previous Medical Device Directive (MDD) to EU MDR compliance underscores its robust quality management systems, continuous process improvement, and alignment with evolving regulatory expectations.

"This recognition is a great achievement by our Kenosha team and represents a significant amount of preparation and execution," said Andreas Weller, President and Chief Executive Officer at Tecomet. "This regulatory achievement not only reflects our commitment to patient safety and product excellence but also ensures our readiness to support our European customers in navigating complex compliance landscapes."

Tecomet successfully upgraded its already MDD-compliant Technical Files to meet the EU's rigorous Medical Device Regulation (MDR). This intensive effort established new compliance benchmarks, reinforcing the Company's dedication to regulatory and product excellence.

"With this certification, Tecomet remains well-positioned to support OEM partners in accelerating innovation while ensuring product integrity and regulatory adherence across the product lifecycle," added Weller. "We look forward to further building partnerships rooted in trust, innovation and continuous improvement, while cementing our long-term commitment to premier quality and regulatory excellence."

About Tecomet

Headquartered in Woburn, Massachusetts, with over 16 facilities worldwide across 3 continents and 5 countries, Tecomet is a global leader in the design, development, and manufacture of orthopedic, robotic assisted, and minimally invasive surgical products. Tecomet provides a full range of metal and material conversion technologies, for long-term implants and instrument solutions, including forging, casting, precision-machining, and other value-add services. Tecomet is also a leading manufacturer of precision components to the aerospace & defense industry, producing products used in aircraft engines, missile & satellite propulsion systems, vision systems, and infrared applications. Tecomet meets the requirements of ISO 9001, AS9100, ITAR, ISO 13485, and for decades has been a steadfast partner of quality to its customers. For more information contact 978-642-2400 or visit www.tecomet.com.

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