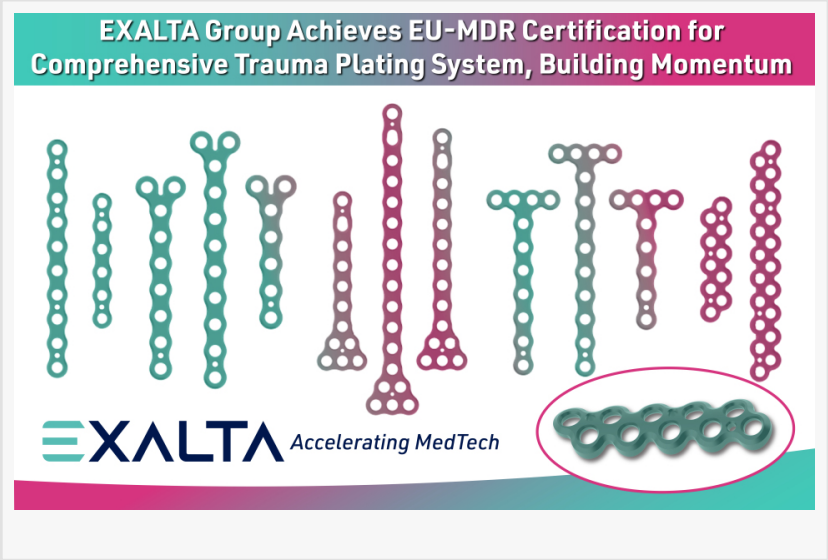
EXALTA Achieves EU-MDR Certification for Trauma Plating System, Building Momentum After Recent Screw Portfolio Approval

BETHLEHEM, PA, UNITED STATES, October 30, 2025 /EINPresswire.com/ -- EXALTA Group, a global leader in manufacturing and integrated OEM solutions for mission-critical medical devices, today announced that it has secured European Medical Device Regulation (EU-MDR) certification across its entire trauma plating system portfolio, spanning both small-bone and large-bone constructs. Available in titanium, these platforms give EXALTA's partners the versatility to address the full spectrum of trauma fixation needs.



By achieving EU-MDR certification for both its compression screw and trauma plating systems, EXALTA now supports extended clinical indications across a complete trauma fixation portfolio. This back-to-back success underscores the company's commitment to regulatory excellence and its ability to help OEM partners access new markets with speed and confidence.

The plating system certification was achieved in record time – just 8.5 months from technical-file submission to approval – highlighting EXALTA's "speed-to-market" promise. With CE Mark coverage now spanning screws and plates, EXALTA's customers can expand their trauma platforms beyond the United States into Europe, one of the world's largest orthopedic markets, effectively doubling commercial opportunity and patient reach.

"Securing EU-MDR for our full trauma plating system highlights the value of EXALTA's model," said Jeff Tyber, President of Commercial and Innovation at EXALTA. "We help our partners cross critical regulatory thresholds faster while our resilient global supply chain ensures continuity, scalability, and quality from launch through commercial expansion. It's about giving customers both speed-to-market and speed-to-revenue."

Obtaining EU-MDR certification is widely recognized as a complex and resource-intensive process that can take companies years to achieve independently. By leveraging EXALTA's integrated OEM solutions, customers gain a proven, accelerated pathway to CE Mark – translating regulatory readiness into faster market access and growth.

"Achieving EU MDR certification for the Trauma Plating System reflects EXALTA's commitment to regulatory excellence and global market readiness," said Lisa Boyle, Vice President of Regulatory Affairs. This achievement serves as a launchpad for global growth, enabling our customers to enter new markets with confidence."

This latest approval further strengthens EXALTA's position as both a trusted manufacturing partner and a strategic OEM solutions provider. With deep regulatory expertise, vertically integrated capabilities, and a global supply chain footprint, EXALTA empowers its partners to scale MedTech innovation worldwide.

About EXALTA Group
With operations across multiple continents, EXALTA Group is a global solutions provider for the MedTech industry. Through its Manufacturing Solutions and Integrated OEM Solutions business units, the company supports leading OEMs in delivering breakthrough medical devices that improve patient outcomes worldwide. Learn more at exalta.com

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