

Life-saving AAJT-S by Compression Works Earns Rigorous MDR Certification

The AAJT-S by Compression Works achieves MDR certification, reinforcing its status as a critical life-saving device for trauma care and emergency medicine.

BIRMINGHAM, ALABAMA, UNITED STATES, July 16, 2024 /EINPresswire.com/ -- <u>Compression</u> Works, Inc., manufacturers of the Abdominal Aortic & Junctional Tourniquet – Stabilized (AAJT-S), announces the certification of their lifesaving medical device using the rigorous MDR (Medical Device Regulation (EU) 2017/745) process recently introduced and required throughout the EU and the UK.



Emergency responders demonstrate the application of the AAJT-S on a training mannequin during a field exercise.

The Medical Device Regulation (MDR),

adopted in April 2017, changes the European legal framework for medical devices and introduces new principal and supportive responsibilities for the European Union (EU) and for national competent authorities in the assessment of certain categories of products. The Regulation entered into force in May 2017 and had a staggered transitional period.

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Achieving MDR certification is a testament to the rigorous standards we've met. We are proud to lead in the hemorrhage control space."

Trey Thorsen of O'Connell & Myers To support the implementation of the MDR, updated guidance on quality requirements for medical devices was prepared, and this new regulatory designation replaces the existing directives for medical devices (<u>93/42/EEC</u> and <u>90/385/EEC</u>).

"This is a significant undertaking," explained Trey Thorsen of O'Connell & Myers, Regulatory Consultant for Compression Works, Inc. "The requirements for this designation are very thorough, and the bar is set quite high. There are very few companies in the hemorrhage control space or the medical device industry, for that matter, that have cleared this hurdle, and we are very proud to be able to claim this distinction."

The AAJT-S is used to stop non-compressible hemorrhage in junctional areas where traditional tourniquets are difficult to place and where the bleeding is most severe. The AAJT-S is also the only FDA-cleared and CE-marked medical device for the prevention of pelvic bleeding and is used in the military and first responder communities at the point of injury to stabilize the patient so that they can be transported to definitive care.

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