

Spineway chooses TUV Rheinland, a leading notified body, for the certification of its products

Spineway, specialized in innovative implants for the treatment of severe disorders of the spinal column (spine), announces its choice of TUV Rheinland as the notified body for the certification of its implant and instrument product lines. With the European regulations governing medical devices constantly changing and ever more stringent, Spineway thus ensures that it will be able to provide high-quality products consistently.

This leading independent organization is known for its reliability and high standards. Spineway's choice underscores its drive to offer quality products and services that meet the highest standards and, in particular, the new medical-devices regulation (MDR) that will enter into effect this coming May.

As TUV Rheinland is MDR accredited, Spineway is ensuring that it will be able to continue manufacturing its products and selling them throughout its market area. The MDR certification process is underway for the reusable surgical instruments, and is progressing in accordance with the timeline given. The entire team is now focused on obtaining this certification for the implants, which will allow the company to continue developing innovative surgical techniques to help both surgeons and patients.

Bolstered by this fully operational regulatory service, Spineway will continue its development so that it can return to a standard level of sales, and will continue to look out for external-growth opportunities that could create synergies.

SPINEWAY IS ELIGIBLE FOR THE PEA-PME (EQUITY SAVINGS PLANS FOR SMES)

Find out all about Spineway at www.spineway.com

This press release has been prepared in both English and French. In case of discrepancies, the French version shall prevail.

Spineway designs, manufactures and markets innovative implants and surgical instruments for treating severe disorders of the spinal column.

Spineway has an international network of over 50 independent distributors and 90% of its revenue comes from exports.

Spineway, which is eligible for investment through FCPIs (French unit trusts specializing in innovation), has received the OSEO Excellence award since 2011 and has won the Deloitte Fast 50 award (2011). Rhône Alpes INPI Patent Innovation award (2013) – INPI Talent award (2015).

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