



SONOVEIN® RECEIVES MDR CERTIFICATION, STRENGTHENING ITS COMMERCIAL POTENTIAL

Malakoff, September 24, 2025, 6:30 pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE), an innovative company developing Sonovein®, a robotic platform for non-invasive High-Intensity Focused Ultrasound (HIFU) varicose vein treatment, announces today that it has received MDR (Medical Device Regulation, EU 2017/745) certification for Sonovein®.

The MDR is the European Union's regulatory framework for medical devices. It is considered one of the strictest in the world, raising the bar for safety, quality and performance in the MedTech industry. The independent assessment confirmed that both the Sonovein® device and Theraclion's quality management system fully comply with the MDR requirements, opening the way for the long-term commercialization of the latest generation of Sonovein®.

"Achieving MDR certification is not just about meeting regulatory requirements," said Martin Deterre, CEO of Theraclion. "It reflects years of continuous improvement, our team's relentless work, and our commitment to providing physicians and patients with innovative treatment solutions that truly make a difference. Coupled with our pivotal trial results, this certification will give a decisive boost to our commercial efforts across Europe and other MDR markets."

Theraclion has held CE Mark certification for Sonovein® under the Medical Device Directive since 2019, with more than 3,500 treatments already performed. The transition to MDR certification not only secures continuity of market access but also reinforces Theraclion's commercial positioning. It provides hospitals, physicians and distributors with greater confidence in the long-term status of Sonovein® and paves the way for faster approval of future product improvements, ensuring patients benefit from the latest advances in non-invasive vein care technology.

About Theraclion

Theraclion is a French MedTech company committed to developing a non-invasive alternative to surgery through the innovative use of focused ultrasound.

High Intensity Focused Ultrasound (HIFU) does not require incisions or an operating room. HIFU treatment concentrates therapeutic ultrasounds on an internal focal point from outside the body.

Theraclion is developing Sonovein®, a CE-marked, robotic HIFU platform for varicose vein treatment, that could replace millions of surgical procedures every year. To date, Sonovein® has been adopted by more than a dozen centers worldwide and used in over 3,500 procedures. In the U.S., Sonovein® is currently limited to investigational use and is not available for sale.

For more information, please visit www.theraclion.com and follow the [LinkedIn account](#).



Theraclion is listed on Euronext Growth Paris

Eligible for the PEA-PME scheme

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