



## THERACLION SECURES KEY CHINESE CERTIFICATION, ADVANCING TOWARD MARKET ACCESS IN CHINA

**Malakoff, October 21, 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 its Sonovein® has successfully passed China's GB 9706.1-2020 medical electrical equipment safety standard — the national equivalent of the internationally recognized IEC 60601-1 normative framework.

This certification confirms that Sonovein® meets the latest Chinese requirements for electrical safety and focused ultrasound emissions for medical devices, validating the robustness of its design and manufacturing processes. It demonstrates Sonovein®'s ability to meet the stringent technical and safety criteria established by the National Medical Products Administration (NMPA), the Chinese regulatory authority.

From a regulatory standpoint, compliance with GB 9706.1-2020 is a pivotal milestone in the NMPA approval pathway, ensuring that Sonovein® fulfills one of the core prerequisites for market authorization in China.

### **Next steps**

This achievement marks significant progress toward market authorization and commercialization in China, one of the world's largest and most dynamic markets for advanced medical technologies. With this certification secured, Sonovein® remains firmly on track to deliver on its international expansion strategy and bring the benefits of its non-invasive ultrasound innovation to a broader patient population.

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### **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 MDR 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 not available for sale.



For more information, please visit [www.theraclion.com](http://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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LEI: 9695007X7HA7A1GCYD29

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