



## **CorWave Achieves Major Regulatory Milestone with ISO 13485 Certification Across its Entire Operations**

**Clichy, France, May 28, 2026 – CorWave, a clinical-stage medical company pioneering innovative cardiac assist devices, announces that its Quality Management System has been certified by an independent notified body in accordance with the international ISO 13485 standard. The certification covers the design, development, manufacturing, distribution, and servicing of implantable Left Ventricular Assist Devices (LVADs). This certification marks a foundational regulatory milestone on the path to commercialization.**

ISO 13485 is the international standard for Quality Management Systems in the medical device industry. It ensures regulatory compliance and guarantees operational excellence and traceability across all product-related processes to maintain quality and safety.

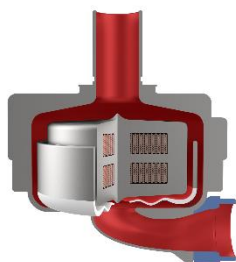
The certification was awarded following a comprehensive audit conducted by an independent notified body. It attests to CorWave’s operational and organizational maturity across the entire product lifecycle of its Left Ventricular Assist Devices: spanning from initial design and development through to manufacturing, distribution, and servicing. This demonstrates CorWave’s ability to manage the entire value chain required for the commercialization of its devices.

*“Implantable ventricular assist devices are among the most complex medical technologies in the world. We have built the infrastructure of operational excellence needed to develop, manufacture, and distribute these devices in-house. ISO 13485 certification is not only a significant regulatory milestone but also reflects our commitment to serving medical teams and their patients with advanced heart failure at the highest level of excellence. This certification allows us to approach our pivotal trial with confidence and will prove decisive for our commercial deployment”,* states Louis de Lillers, CEO of CorWave.

*“We are proud of the work accomplished by our teams. The certification of our internal processes reflects our commitment to rigorous risk management, patient safety, and the operational excellence required by our products”,* adds Dawn Sadlowski-Buisserez, Vice President of Operations at CorWave.

With this certification, CorWave takes a decisive step toward achieving its ambition: save heart failure patients and offer them an active life.

## About CorWave



CorWave is a French company that develops and manufactures innovative cardiac assist devices. CorWave's undulating membrane is a breakthrough technology that distinguishes itself from currently marketed Left Ventricular Assist Devices (LVADs) through its physiological operation, designed to reproduce pulse and blood flow velocities similar to those of a healthy heart. Ultimately, CorWave's membrane pump technology is designed to reduce complications associated with current devices and improve the management of patients suffering from heart failure. A member of French Tech 120, CorWave was founded in 2012 by the start-up studio MD Start and is funded by renowned investors, including Bpifrance, EIC Fund, M&L Healthcare, Novo Holdings, Seventure Partners, Sofinnova Partners, Ysios Capital, and Vlerick Group. The company

has raised over 100 million euros in equity funding and employs about a hundred people. In May 2025, after more than a decade of research and development, CorWave became the first company in over 25 years to bring a radically new pumping technology into clinical evaluation in the durable LVAD space.

Further information: [www.corwave.com](http://www.corwave.com) | [x.com/corwave](https://x.com/corwave) | [www.linkedin.com/company/corwave](https://www.linkedin.com/company/corwave)

*CorWave LVAS is a medical device currently available for clinical investigations only.*

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*CorWave's industrialization program is supported by Île-de-France region through the « Relance Industrie » call for projects.*