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Medtronic receives CE Mark for VitalFlow™ ECMO System, ushering in a new era of critical care in Europe

Medtronic expands its cardiac surgical and respiratory innovation portfolio with the launch of the VitalFlow ECMO System

Medtronic plc, a global leader in medical technology, today announced a major advancement in its mission to transform critical care – the VitalFlow™ Extracorporeal Membrane Oxygenation (ECMO) System has officially received CE (Conformité Européenne) Mark approval in Europe. This milestone signals a significant leap forward in delivering seamless, life-saving support to the most fragile patients. With the CE Mark secured, Medtronic now offers a simple, fully integrated ECMO portfolio in Europe, purpose-built to meet the complex and evolving demands of modern intensive care units.

A Legacy of Innovation

The roots of ECMO innovation trace back to the 1960s and 70s, when Dr. Robert Bartlett – widely regarded as the "father of ECMO" – pioneered heart-lung bypass research that laid the foundation for today's life-sustaining systems. His vision led to the founding of MC3 Cardiopulmonary in 1991, a company dedicated to developing safe, high-performing ECMO technologies for both adult and pediatric patients.

The VitalFlow ECMO technology is the most innovative technology to-date from the Medtronic acquisition of MC3 Cardiopulmonary. The acquisition marked the culmination of an eight-year partnership and distribution agreement with the Medtronic Cardiac Surgery business resulting in the introduction of seven new ECMO products in seven years. MC3 Cardiopulmonary consistently developed and manufactured differentiated, high-quality ECMO products, which were exclusively distributed by Medtronic prior to the acquisition. These products, including catheters and oxygenators, are distinguished by their ability to simplify therapy and enhance ease of use. Additionally, the partnership has reliably supplied these long-term indicated products throughout the COVID pandemic and beyond. With the CE Mark for VitalFlow achieved June 2025, the company is now poised to redefine ECMO care across Europe.

VitalFlow System: ECMO Reimagined

The VitalFlow System represents a new paradigm in ECMO therapy. Designed to simplify ICU operations, it brings performance, ease of use and adaptability to the forefront of patient care. Its intuitive interface empowers every ICU team member – regardless of experience level – to operate ECMO with confidence and precision.

With high performance, simplicity, and a configurable, upgradeable architecture, VitalFlow ECMO is more than a

system – it is smart, scalable, and built to support the future of critical care.

A Commitment to Patients

"The CE Mark for the VitalFlow ECMO System is a powerful reflection of how we bring the Medtronic Mission to life — by engineering technologies that restore health and extend life," said Giuseppe Savoja, Western Europe senior business director for the Cardiac Surgery business, which is part of the Cardiovascular Portfolio at Medtronic. "VitalFlow ECMO is more than a system; it's a step toward transforming how ECMO is delivered across Europe. By simplifying complexity and expanding access, we're helping care teams focus on what matters most – saving lives and improving outcomes for critically ill patients."

As the only company serving the entire heart care team – from cardiac surgeons to perfusionists – Medtronic continues to lead in heart valves, surgical ablation, left atrial appendage management (LAAM), revascularization, perfusion, cannulation technologies and ECMO therapies. This comprehensive approach empowers clinicians to deliver holistic, lifetime care for their patients.

"Clinicians in the ECMO space have evolving needs," said Pieter Kappetein, Ph.D., M.D., chief medical officer, Cardiac Surgery, Medtronic. "With patients' diseases becoming more complex, there is a growing demand for innovative solutions such as the VitalFlow ECMO system. Clinicians expect more from Medtronic and we are uniquely positioned to meet these needs to better serve their patients."

About ECMO

ECMO uses a pump and oxygenator outside of the body to take over the work of the heart and lungs to restore health and extend life to critically ill patients who might otherwise expire. ECMO is most often used for life-threatening heart or lung failure to allow the heart and/or lung to rest and heal. It is also used as a bridge option to heart or lung transplantation or to further treatment such as heart assist device or left ventricular assist device (LVAD).

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow Medtronic on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the U.S. Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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