
LivaNova Announces Receipt of Close-Out of Warning Letter from U.S. Food and Drug Administration

London, December 13, 2022 – LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology and innovation company, today announced it received a close-out letter from the U.S. Food and Drug Administration (FDA) for the Warning Letter the Company received on December 29, 2015 that was associated with its Munich, Germany facility and 3T Heater-Cooler™ device. Closure of the 2015 Warning Letter represents the culmination of LivaNova’s corrective actions implemented at its Munich manufacturing facility and to the 3T Heater-Cooler device design.

“We are pleased to have received the close-out notification from the FDA, and we appreciate the agency’s collaboration throughout this extensive process,” said LivaNova CEO Damien McDonald. “I would like to thank the team at LivaNova and our partners for their commitment and resilience during this period. Quality is at the center of every action we take at LivaNova, and we diligently addressed the concerns raised by FDA to ensure we continue to provide safe and effective products to our patients in the U.S. and around the world.”

About LivaNova

LivaNova PLC is a global medical technology and innovation company built on nearly five decades of experience and a relentless commitment to provide hope for patients and their families through innovative medical technologies, delivering life-changing improvements for both the Head and Heart. Headquartered in London, LivaNova employs approximately 3,000 employees and has a presence in more than 100 countries for the benefit of patients, healthcare professionals and healthcare systems worldwide. For more information, please visit www.livanova.com.

Safe Harbor Statement

This news release contains “forward-looking statements” concerning the Company’s goals, beliefs, expectations, strategies, objectives, plans, and underlying assumptions and other statements that are not necessarily based on historical facts. These statements include, but are not limited to, statements regarding the 2015 FDA Warning Letter, the related close-out letter and the 3T Heater-Cooler device. Actual events may differ materially from those indicated in our forward-looking statements as a result of various factors, including those factors set forth in Item 1A of the Company’s most recent Annual Report on Form 10-K, as supplemented by any risk factors contained in Quarterly Reports on Form

10-Q and Current Reports on Form 8-K. LivaNova undertakes no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

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