Press release 2026-09-17

Monivent receives MDR certification for Neo100

Monivent AB ("Monivent" or the "Company") announces that its product Monivent Neo100 has received CE certification in accordance with the EU Medical Device Regulation, MDR (Regulation (EU) 2017/745). The certification has been issued by the independent Notified Body BSI and confirms that Neo100 meets the applicable EU requirements for safety, performance and regulatory compliance for Class IIb medical devices. The certification represents a major regulatory milestone for Monivent and enables the Company and its distribution partner Dräger to proceed with the planned joint launch of Neo100 in the European market.

Neo100 was previously CE marked under the Medical Device Directive (MDD), the regulatory framework that preceded the MDR. Monivent submitted its application for MDR certification to BSI in 2023 and has since undergone an extensive regulatory review process, including comprehensive assessments of the product's technical and clinical documentation, additional testing and the submission of supplementary documentation to demonstrate compliance with the more stringent requirements introduced under MDR.

Beyond enabling the planned European launch, the transition to MDR provides a robust regulatory framework for the continued development of Neo100 and for implementing future product improvements, including those based on customer feedback from the product's first years on the market. MDR certification may also facilitate regulatory pathways in certain markets outside the EU, including Australia. Monivent intends to actively evaluate opportunities for additional market registrations.

"Receiving MDR certification is a major milestone for Monivent and the result of several years of intensive work by the entire team. Most importantly, it clears the regulatory path for the planned European launch of Neo100 together with Dräger and marks the beginning of an important new commercial phase for Monivent" says Maria Lindqvist, CEO of Monivent.

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This is information that Monivent AB is obligated to disclose pursuant to the EU Market Abuse Regulation (EU No 596/2014). The information was submitted for publication, through the agency of the contact person set out above, on 17 September 2026 at 11.55 CEST.

***Monivent AB** ("Monivent") develops, manufactures and sells medical devices in order to improve the emergency care provided to newborns in need of respiratory support at birth. About three to six percent of all newborns end up in this critical situation and healthcare professionals today lack good tools to determine how effective this manual ventilation is. Monivent has developed equipment that measure the airflow to the child directly in the face mask via a sensor module that sends data wirelessly to an external monitor. The caregiver thereby receives immediate feedback, which enables necessary adjustments to support an effective but at the same time gentle treatment. The company is also marketing a product for simulation-based training on manikins, building on the same technology as the clinical product.*