PRESS RELEASE
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LIFECARE RECEIVES PRELIMINARY ASSESSMENT FROM NOMA IN FIRST-IN-HUMAN STUDY APPLICATION

Bergen, Norway, 11 December 2025 - Lifecare ASA (LIFE), a MedTech company developing next generation Continuous Glucose Monitoring (CGM) technology for diabetes management, announces that it has received a preliminary assessment from the Norwegian Medical Products Agency (NoMA) regarding the company's application to initiate its first-in-human clinical study.

NoMA's preliminary assessment is a normal and expected step in the standard review process for medical device investigations under Regulation (EU) 2017/745 (MDR). As part of routine procedure, NoMA has requested additional information - a clarification step that can occur at any point in the review. When this happens, the review timeline is paused until updated documentation is provided.

NoMA has emphasized that its request relates to procedural and technical clarifications, which are typical for first-in-human implantable devices. Importantly, NoMA has not questioned the scientific rationale, intended use, or overall risk-benefit basis for conducting the study.

NoMA has informed Lifecare that it has used 39 of the standard 45 review days, and that the review clock is now paused. Once Lifecare submits the requested updates, NoMA will have 26 days remaining to complete its assessment and issue a decision, reflecting the MDR-permitted flexibility to extend review time by 20 days when expert input is required.

Lifecare is preparing its response and updated documentation in close collaboration with its partners and expects to submit the updates within the coming weeks.

As previously communicated, Lifecare's application covers the pilot study for the accuracy and clinical performance evaluation of the company's proprietary CGM system, consisting of an implantable sensor, software, and read-out device. The study is planned to take place at the University of Bergen, under the supervision of Professor Simon Dankel as Principal Investigator.

Outlook
NoMA's request for additional information is fully in line with normal regulatory procedure and reflects the agency's detailed evaluation of complex medical devices. Based on the current communication, final decision is now expected in Q1 2026.

As a matter of financial responsibility and good governance, Lifecare will not initiate the production of implants intended for the first-in-human study before NoMA has granted authorization. This means that the study timeline will naturally align with the regulatory process and the subsequent availability of manufactured devices.

The pilot study will generate critical data for Lifecare's pivotal CE-marking trial planned for 2026 and supports the company's roadmap towards European market launch in 2027.

About us

Lifecare ASA is a medical sensor company developing technology for sensing and monitoring of various body analytes. Lifecare's focus is to bring the next generation of Continuous Glucose Monitoring systems to market. Lifecare enables osmotic pressure as sensing principle. Lifecare's sensor technology is suitable for identifying and monitoring the occurrence of a wide range of analytes and molecules in the human body and in pets.

Contacts

For further information, please contact:

Joacim Holter, CEO, joacim.holter@lifecare.no, +47 40 05 90 40

Renete Kaarvik, CFO, renete.kaarvik@lifecare.no, +47 94 83 82 42