

LIFECARE RESUBMITS APPLICATION FOR FIRST-IN-HUMAN CLINICAL STUDY

Bergen, Norway, 15 September 2025 – Lifecare ASA (LIFE), a MedTech company developing next generation of Continuous Glucose Monitoring (CGM) technology for diabetes management, today announces that it has resubmitted its application to the Norwegian Medical Products Agency (NOMA) for authorization to initiate the company's first-in-human clinical study.

As part of a normal regulatory process, NOMA has provided feedback to ensure that the study meets regulatory, scientific, and safety requirements. Lifecare has carefully addressed comments received from NOMA, based on our initial application. We have updated the documentation in line with the agency's guidance, ensuring compliance with the latest regulatory requirements, and resubmitted the application.

The application covers the first-in-human pilot study with Lifecare's proprietary CGM system consisting of an implantable sensor, software and read-out device. The study is designed to confirm safety, tolerability, and glucose measurement performance.

Lifecare expects that the initial approval from the Norwegian Regional Committee for Medical and Health Research Ethics (REK) will be reissued, as the committee has already granted approval subject only to minor documentation updates.

Lifecare's CEO, Joacim Holter, comments:

"We welcome the feedback from NOMA, which has helped us strengthen our submission. The resubmission is an important forward step in our regulatory pathway and demonstrates our commitment to meeting the highest standards for patient safety and product quality. We remain on track with our strategy and timelines, and this is another milestone on our way to making our innovative sensor technology available to people with diabetes."

This first-in-human study will pave the way for Lifecare's pivotal CE-marking study, scheduled for 2026, and the planned European commercial 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 ("CGM") 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.

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