

LIFECARE RECEIVES UPDATE FROM NOMA ON HANDLING TIME FOR FIRST-IN-HUMAN STUDY APPLICATION

Bergen, Norway, 28 October 2025 – Lifecare ASA (LIFE), a MedTech company developing next generation Continuous Glucose Monitoring (CGM) technology for diabetes management, announces that it has received an update from the Norwegian Medical Products Agency (NOMA) regarding the handling time for the company's application to initiate its first-in-human clinical study.

In line with the company's announcement of 15 September 2025, in which Lifecare reported the resubmission of its application as part of a normal regulatory process, NOMA has now confirmed validation of the application and that the documentation is considered complete in accordance with Regulation (EU) 2017/745 (MDR), Article 70.

Following validation, NOMA has informed that the scientific assessment phase has commenced and will follow a standard handling time of 45 days from the validation date of 23 October 2025. This period may be extended by up to 20 days if external expert consultation is required or temporarily paused should NOMA request additional documentation.

The application covers Lifecare's pilot study for the accuracy and clinical performance evaluation of its proprietary continuous glucose monitoring system, consisting of an implantable sensor, software, and read-out device. The study will be conducted at the Research Unit for Health Surveys, University of Bergen, under the supervision of Professor Simon Dankel as Principal Investigator.

Based on NOMA's communicated handling time, final regulatory approval can at the earliest be expected mid-December 2025. Lifecare expects the study initiation to take place in Q1 2026.

The pilot study will form an important foundation for Lifecare's pivotal CE-marking trial planned for 2026, leading to the company's 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 ("**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.

Contacts

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