

DEARhealth becomes one of the world's first companies to obtain CE-marking according to new European Union Medical Device Regulation (MDR)

AMSTERDAM, June 9, 2021 /PRNewswire/ -- DEARhealth, a health tech company focused on AI-powered chronic disease management, today announced that it has obtained certification for ISO 13485 (quality management systems for medical devices) and the certificate of conformity according to the European Union Medical Device Regulation (MDR) as a class IIa medical device for the first release of the DEARhealth patient and care software. With this certification, DEARhealth has demonstrated the ability to build, maintain, and manage the complete lifecycle of a software as a medical device. The CE-mark allows DEARhealth to market its medical software commercially in the European Union.

CE-marking according to MDR assures health systems and pharmaceutical companies that a software as a medical device complies to European Union regulation and meets a high standard of quality and safety requirements.

"Worldwide, MDR is the most rigorous regulation for medical software," said Daniel Hommes, DEARhealth Founder and Chief Medical and Product Officer. "Our partners in both the US and Europe can be confident that we design and manufacture our medical device software under high standards of quality and safety. DEARhealth validated remarkable health outcomes and efficiencies as clinical evidence to demonstrate conformity to the regulatory requirements."

Following a successful conformity assessment, including an audit of the quality management system, DEARhealth is among the first 250 manufacturers to obtain CE-marking according to MDR for their medical device software.

"We're very proud to obtain CE-marking in such a short time, which is an incredible achievement," said Katinka de Korte, DEARhealth's Person Responsible for Regulatory Compliance. "Obtaining the CE-mark and certification for ISO 13485 enables DEARhealth to accelerate collaboration with health systems across Europe."

About DEARhealth

DEARhealth is a health tech company founded in 2013, by University of California, Los Angeles (UCLA) medical experts to transform healthcare by using AI-powered care pathways for chronic disease management. DEARhealth is a validated, AI-driven medical device software that has been successfully implemented in large health systems, in disease areas such as inflammatory bowel diseases, epilepsy, rheumatology and ovarian cancer. DEARhealth's partners include health systems, providers, payers, and pharmaceutical companies globally. Investors in DEARhealth include Philips Health Technology Ventures, Vesalius Biocapital III, the European Investment Fund, and Health Innovations. To learn more about DEARhealth visit <https://www.dearhealth.com> or contact info@dearhealth.com.