

ARTIFICIAL INTELLIGENCE: ALMAWAVE AMONG THE FIRST COMPANIES IN EUROPE TO CERTIFY THE USE OF AI IN MEDICAL DEVICE AREA

- **The company further strengthens its healthcare positioning**
- **On the strength of this initial objective, Almawave plans to extend the MDR certification process also to other AI application cases**

Rome, February 12, 2024 - Almawave, an Italian company listed on the Euronext Growth Milan market (*Ticker: AIW*), a Data & Artificial Intelligence player, part of the Almagroup, further strengthens its positioning in the healthcare field, obtaining prestigious certifications for the use of Artificial Intelligence in this sensitive sector that requires strict compliance with the authorities' standards.

Almawave, over the past two years, has worked to obtain two prestigious certifications in the healthcare field - issued by the DNV certifying body - synonymous with authority and the quality of its offerings. The first, in accordance with the international standard ISO 13485, certifies the business management system for the development of healthcare software to support clinical decision-making; the second, in accordance with the European Medical Device Regulation 2017/745 (MDR), certifies compliance with regulatory requirements related to the design, manufacture, and marketing of medical devices in European Union countries. In 2021, the requirement for this type of certification was also extended to Artificial Intelligence-based applications.

Almawave is therefore one of the first companies in Europe to have MDR certification issued by a Notified Body. This important certificate is related to "DevAlce", an AI application-based Medical Device solution developed in-house by the Almawave team and successfully validated in an operative clinical trial. Specifically, such a solution, linked to the Covid pathology, enables the creation of an indicator for predictive risk stratification for use in telemedicine. This, by facilitating the remote monitoring of patients and thus providing basic physicians with information on disease progress, allows for accurate analysis of the patient's condition and the processing of valuable information to support medical personnel.

"I am very happy that Almawave has achieved these important certifications. Artificial intelligence will certainly be able to support not only the efficiency of healthcare, but also of improving people's quality of life, commented Valeria Sandei, CEO of Almawave. "What is important is that the adoption of potential new technologies in the telemedicine area is always accompanied by strict criteria focused on protecting people. MDR certification, particularly on innovative issues such as those we deal with, is a long and complex journey, but one focused on ascertaining technical and clinical aspects of primary importance."

The use of Artificial Intelligence in the Medical Device field will bring multiple and significant benefits to the healthcare system in terms of patient monitoring and the efficiency and quality of the support system and of telemedicine. According to the most recent regulatory



developments, the application of AI in the Medical Device field requires the certification of technical and clinical aspects for compliance by a notified body and the achievement of a CE certificate.

The company on the strength of this first, important goal, now plans to extend the MDR certification process to other AI application cases that have been studied and tested over time for different pathologies, such as Oncology.

In addition to this highly distinctive national and international certification, the ISO 13485 certification also further complements and strengthens Almaxwave's positioning in the healthcare arena. Also achieved through the independent DNV Entity, it certifies the company's management of the design, development, production, installation, support service and marketing of healthcare software for clinical decision support and patient and disease management. Applicable therefore to the entire spectrum of healthcare, the certification represents a factor proving the solidity and acceleration of the company in this sector.

Almaxwave profile

Almaxwave S.p.A. is an Italian company, listed on the Euronext Growth Milan (AIW.MI) market and engaged in the field of Data & Artificial Intelligence. The Group offers proprietary technologies, solutions and services which realize AI and data's potential in the digital evolution of companies and public administrations. It boasts more than 300 domestic and international clients, in sectors including Government, Finance, Energy & Utilities, Tourism and Healthcare, operating directly and through partners. The Almaxwave team consists of more than 400 professionals. The Group uses AI technology labs dedicated to developing products, platforms and vertical solutions targeting various market segments. Almaxwave's technological asset base, conceived and built as a model of natural experience in the interaction between man and machine, can interpret text and voice in over 40 languages, interacting in multi-channel mode, analyzing data and information with a view to knowledge development and automation to support decisions. Its skill centers also allow the potential of data to be achieved in complex contexts, combining expertise on key market frameworks in areas such as Data Management, Machine Learning, Location Intelligence, and the knowledge of business processes in related vertical sectors. The Almaxwave scope, part of the Almaxviva Group, includes the companies SisTer, The Data Appeal Company, Mabrian Technologies, Obda Systems, Almaxwave do Brasil, and Almaxwave Usa. www.almaxwave.com

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