MSCopilot® receives CE marking under the European Union Medical Device Regulation (EU MDR) 2017/745

A major milestone for the digital monitoring of people living with multiple sclerosis

PARIS, FRANCE, FRANCE, June 3, 2025 /EINPresswire.com/ -- On the occasion of World Multiple Sclerosis Day, Ad Scientiam announced that MSCopilot®, its class IIa Software as a Medical Device (SaMD) dedicated to the monitoring of people living with multiple sclerosis (MS), has received CE marking under the European Medical Device Regulation (EU MDR) 2017/745, demonstrating compliance with strengthened requirements for safety, clinical performance and benefit.

This recognition confirms compliance with applicable regulatory obligations and further reinforces MSCopilot®'s legitimacy in the field of neurology. It also reflects Ad Scientiam's ongoing commitment to developing rigorously validated digital biomarkers and patient-centered solutions that meet the highest standards of quality and clinical value.

A flagship digital solution for MS monitoring
MSCopilot® enables people living with MS to autonomously perform targeted self-assessments, from their smartphone, of four key functional domains frequently impaired by the disease: walking, manual dexterity, cognitive function, and low-contrast visual acuity.

The results are accessible to healthcare professionals through a secure dashboard, supporting personalized, structured and longitudinal patient monitoring.

This milestone reflects more than a decade of research and development in MS. Two clinical studies conducted in collaboration with expert centers have demonstrated strong correlations between MSCopilot®'s digital outcomes and gold-standard clinical assessments.

The results of these studies have been published in three peer-reviewed scientific journals (European Journal of Neurology (EJN), Multiple Sclerosis and Related Disorders (MSARD) and the

Multiple Sclerosis Journal (MSJ)) and presented in ten posters/oral communications at international scientific events, in partnership with leading pharmaceuticals companies such as Biogen, Roche, and Novartis.

A rigorous quality management system
Ad Scientiam's ISO 13485 certification, obtained in 2020 and renewed in 2023, attests to the implementation of a robust quality management system tailored to the specific requirements of medical devices, addressing the full product lifecycle, from development to post-market surveillance.
Both CE-marking and ISO 13485 certifications are the result of a rigorous, collective effort, carried out in close collaboration with notified bodies and end users.

Driving innovation to meet the needs of patients and healthcare providers
Following the CE marking of MSCopilot®, Ad Scientiam is actively pursuing its regulatory roadmap, including targeted deployment across European markets by the end of 2025, and a marketing authorization submission to the FDA, aiming for a commercial launch in the United States in early 2026.

Achieving CE marking represents more than a regulatory milestone: it is a key step in our mission to meaningfully transform the monitoring of people living with MS.

About Ad Scientiam
Ad Scientiam is committed to improving patient care by continuously monitoring the progression of severe and disabling diseases in real-life settings. This approach is essential for delivering more effective, personalized care.

To address this need, Ad Scientiam develops and clinically validates digital biomarkers that follow and identify small and hardly detectable disease fluctuations. These biomarkers are derived from data collected through digital tools like smartphones and are processed using proprietary algorithms.

The company's expertise has been recognized by leading hospital institutions, such as the Paris Brain Institute (ICM), as well as major pharmaceutical companies including Sanofi, Kyowa Kirin, Vertex, Merck, and Biogen.

In addition to MSCopilot®, its CE-marked Software as a Medical Device for the self-assessment of people living with multiple sclerosis, Ad Scientiam is validating new medical devices across various fields, including neuroscience, rare diseases, and mental health. Ad Scientiam's Quality Management System is fully compliant with ISO 13485.

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