machineMD’s neos™ Receives EU-MDR Class IIa Certification, Marking a Breakthrough in Neuro-Ophthalmic Diagnostics

machineMD announces its visionary medical device, neos™, is certified as a Class IIa medical device under the EU Medical Device Regulation by TÜV SÜD Danmark.

machineMD ISO13485 - neos CE Mark

machineMD

BERN, SWITZERLAND, October 16, 2024 /EINPresswire.com/ -- machineMD, a Swiss medical device company innovating at the intersection of neuroscience and ophthalmology, is proud to announce its visionary medical device, neos™, is certified as a Class IIa medical device under the European Union Medical Device Regulation (EU-2017/745 MDR) by TÜV SÜD Danmark (NB 2443).

This certification sets a new standard in the fields of neurology and ophthalmology, making neos™ the first EU-MDR medical device that comprehensively assesses eye movements, pupillary function, and visual fields.

Already in use by neurologists, ophthalmologists, and optometrists in Switzerland and the USA, neos™ is making a significant impact in clinical practice. neos™ has the potential to inform millions of examinations each year with objective and quantifiable measurements, supporting the diagnosis and monitoring of neuro-ophthalmic conditions such as double vision and vision loss.

The neos™ examination enables patients to watch an intuitive sequence of gamified graphics via an industry-leading VR headset, which measures the resulting eye movements and pupillary changes of each eye. With examination sequences as short as 3 minutes, and operable by a medical assistant or technician, neos™ is poised to bring significant efficiency gains to clinical workflows.

The machineMD team originally began developing neos™ at the University Hospital of Bern,

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>
> *Dominic Senn, CEO*

Inselspital, adding to decades of clinical research in neuro-ophthalmology. The innovative project was propelled forward with additional partners CSEM and Helbling Technik, co-financed by Innosuisse.

Medical Director and co-founder, Dr. Mathias Abegg, explains, “We see an acute need to equip all levels of healthcare professionals to perform functional vision assessments, particularly from the perspective of the vast majority of patients who present their first symptoms in primary and secondary care.”

In addition to the certification of neos™, machineMD is also proud to announce that the company’s Quality Management System has been certified as compliant with the ISO 13485:2016 standard for Medical Devices by TÜV Italia. This certification covers the design and development, manufacturing, and placing on the market of active non-implantable devices, further demonstrating machineMD's dedication to quality and excellence in the fields of neurology and ophthalmology monitoring and diagnosis.

"The EU-MDR Class IIa certification for neos™ underscores our commitment to providing innovative devices that enhance the capabilities of healthcare professionals in neurology and ophthalmology," said Dominic Senn, CEO and co-founder. “This is a significant enabler for precision medicine, and further enables our research collaborations for people with Parkinsons’, Multiple Sclerosis, Myasthenia and other rare diseases.”

About machineMD
machineMD is a medical device company, headquartered in Switzerland, with a subsidiary in Boston, USA, that is innovating at the intersection of neuroscience and ophthalmology. The company’s mission is to radically improve the measurement of brain function, with a vision for a world where people receive an accurate, fast, and early diagnosis of brain disorders
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