

MANUS NEURODYNAMICA LIMITED

ISO Certification of Quality Management System

Validates Manus as a medical device company allowing the Company to fully engage in commercial activities

Edinburgh, UK – 17 June 2021: Manus Neurodynamica Limited (“Manus”), which develops and markets products and technologies for neuromotor assessment, announces that it has received ISO 13485:2016 certification following an assessment of its Quality Management System (“QMS”), validating the NeuroMotor Pen™ (NMP) manufacturing process as well as the organisation and its management procedures.

The accreditation and registration as a medical device manufacturer are significant milestones in the development of the Company. It confirms that the internal processes as well as the formalised relationships, including suppliers and clients and regulators, are meeting the regulatory standards. The certification validates Manus as a medical device company with significant advantages over many healthtech companies, whose tech offering are not registered medical devices.

The QMS system defines a positive and self-organising culture. This achievement sets a solid foundation for launch into the clinical markets that enables commercial growth and having received this certification, the Company can fully engage in commercial activities. These include: engaging with the NHS and purchasing hubs; easier engagement with reputable distributors and strategic partners; making adoption easier for pharmaceutical companies; preparing future submissions outside Europe; and launching with confidence in the US, once the first FDA approval has been obtained.

A total of £5m of new funding has been raised to date, including a £750,000 financing round, closed in May last year, led by HealthTech investors Par Equity with support from the Scottish Investment Bank, the investment arm of Scottish Enterprise, and Old College Capital. In addition, Manus had also received a £600k grand award from Innovate UK for diversification into Alzheimer’s and other dementias, and the overall project goal is to optimise and validate NMP for screening of Dementias.

Dr Rutger Zietsma, CEO of Manus, commented: *“We are so pleased to have been accredited with this ISO standard as it serves to recognise a key milestone in the development of the Company. There is a natural sequence to the events that need to take place when taking a medical device to market and developing the organisation to support the launch and post-launch activities is crucial. Now all this essential work has been completed, Manus can fully engage in its commercial activities.”*

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Notes to Editors

***About Manus Neurodynamica* - www.manusneuro.com**

Dr Rutger Zietsma founded Manus in August 2008. The Company's main activity is designing, patenting and marketing innovative technologies used in medical devices and personal care products which have the capability to improve people's health and wellbeing. The Company implements quality procedures to medical standards.

Its principal product is a sensory pen designed for use in the diagnosis and monitoring of neuromotor impairments. The pen particularly focuses on patients with Parkinson's disease and uses limb and hand motion to diagnose patients quickly and non-invasively. It has applications across not just diagnosis but also screening, monitoring, rehabilitation and drug development for a number of different movement disorders.

About NeuroMotor Pen™

NeuroMotor Pen™ (NMP) is a unique, patented and CE-marked system that combines sensor technologies built into a digital pen with software and an analytical engine with Decision Support System. The interface enables users to record non-invasively and analyse parameters of minute limb and hand motion. This enables quantification of fine motor skill. These parameters are used as 'digital biomarkers' to provide objective information about movement abnormalities. NMP can be used to support diagnosis and monitoring of Parkinson's Disease and other neuromotor impairments. It has the potential to be a quick, inexpensive, non-invasive, and objective aid to diagnosis that can provide a low-cost alternative to brain scans.