

## PRESS RELEASE

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**RESTORATIVE NEUROTECHNOLOGIES (RNT)  
REINFORCES ITS LEADERSHIP IN DIGITAL THERAPIES  
FOR COGNITIVE REHABILITATION  
THROUGH THE EUROPEAN HEALTHCARE CERTIFICATION  
OF MINDLENSES PROFESSIONAL™ AS A CLASS IIA CE-MARKED MEDICAL DEVICE**

PALERMO/TURIN, July 17<sup>th</sup>, 2024 - The RNT **MindLenses Professional™** digital therapy for the rehabilitation of the cognitive functions of patients in post-stroke has been **certified as a Class Ila Medical Device under the new European Union Medical Device Regulation (MDR) 2017/745**. RNT is **the first Italian Medtech company to obtain a MDR based Class Ila certification for cognitive rehabilitation**, setting a new industry standard and paving the way to European commercialization.

MindLenses Professional™ is an **innovative and non-invasive digital therapy** that combines neuromodulation through the use of prismatic lenses together with a suite of serious games developed by neurologists and psychologists and used by the patients, as well as a Web portal allowing the physicians to **access patient and clinical data**. Two clinical trials carried out during the last three years have demonstrated the clinical performances and benefits of MindLenses Professional™ for the **rapid rehabilitation of impaired cognitive functions** (for example: attention, language, memory and ability to interact socially) of patients following a **stroke**. Similar clinical evidence and performances have been demonstrated for patients suffering from neurodevelopmental disorders, particularly **ADHD** (Attention/Deficit Hyperactivity Disorder) and **Dyslexia**. The main competitive advantages of MindLenses Professional™ consist in a **shorter protocol (10 days)** instead of the weeks or months of the alternatives, together with higher clinical outcomes for the rehabilitation of the cognitive functions of the patient (**30% higher** compared to alternatives) with long-term benefits.

MindLenses Professional™ is already on the market in Italy as a Class I Medical Device and already adopted by **50 major public and private hospitals and rehabilitation centers in 12 months of commercialisation**. Over 1800 patients have already benefited from the MindLenses Professional™ digital therapy benefits for cognitive rehabilitation, either through the clinical trials or through the prescription of the therapy by healthcare professionals in Italy.

"The impact of this European certification is enormous," said RNT's CEO **Laurent Vandebrouck**. "The MDR CE-Marking certification as a Class Ila Medical Device not only underscores our commitment to excellence but also **gives MindLenses Professional™** a crucial **competitive edge in the European market**, where regulatory compliance and medical device security and benefits are paramount. The certification means that MindLenses Professional™ can now be fully commercialized throughout Europe - a launch we have been preparing for a year by signing several deals with medical device distributors and service providers in Europe. They will now be in the position to resell MindLenses in their own regional hospitals, allowing local patients in post-stroke to access this competitive

digital therapy to more rapidly recover and improve their cognitive functions and quality of life. This will also reduce the workload of the physicians for the execution of the rehabilitation protocols of patients in post-stroke”.

The European Union’s Medical Device Regulation replaced the earlier Directive 93/42/EEC (MDD), with the purpose of ensuring that medical devices are safe and perform as intended. The rigorous certification process, which took two years, subjected MindLenses Professional™ to comprehensive assessments of the product’s **technical documentation, clinical evaluations and evidence, patient outcomes** and the implementation of a robust **Quality Management System** - the latter already certified according to ISO 13485 in 2022.

“MindLenses Professional™ is now **eligible for inclusion in reimbursement pathways** within national public health systems in Europe,” continues Vandebrouck. “We are starting procedures to enter national healthcare systems in Europe through our local distributors and resellers, including reimbursement paths reserved to CE-marked digital therapies”.

“MindLenses Professional™ has just become one of the first digital therapies for cognitive rehabilitation to comply with the new EU regulation”, says **Agnese Di Garbo**, Co-Founder, and QARA & Clinical Director for RNT, who leads the certification project. “The Class IIa certification is a **testament to the safety, efficacy, and quality of MindLenses Professional™**, affirming its capability to meet stringent regulatory requirements and to be at the forefront of its market. It has been a long process but we are satisfied with this achievement”.

“The logic behind MindLenses Professional is the neuromodulation of specific brain circuits underlying cognition”, says **Massimiliano Oliveri**, neurologist, Founder, President of the Board, and Chief Scientific Officer at RNT. “Following this approach, MindLenses Professional aims to be a digital therapy for cognitive rehabilitation in different **neurological and neurodevelopmental disorders**. The next step will be the extension of the certification under MDR for **ADHD** (Attention/Deficit Hyperactivity Disorder), **Dyslexia** as well as for **Mild Cognitive Impairment** and **dementia**.”

### **About Restorative Neurotechnologies**

Restorative Neurotechnologies is a pioneer in developing innovative medical devices for cognitive health and neurorehabilitation. The company was founded in 2018 in Palermo by Massimiliano Oliveri, neurologist, Harvard-trained scientist and Professor of Cognitive Neuroscience at the University of Palermo. Restorative Neurotechnologies raised approximately 3M€ from public and private investors. MindLenses Professional is a medical device used in the cognitive rehabilitation of stroke, sold directly and through specialized distributors in the European Union. For more information, visit [www.restorativeneurotechnologies.com](http://www.restorativeneurotechnologies.com) and social media pages.

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### **Contact:**

Martina Puppi, Marketing & Communications Manager

[martina.puppi@restorativeneurotechnologies.com](mailto:martina.puppi@restorativeneurotechnologies.com) || +39 328 9757541