

QM 00 A4

V. 00

Prepared by

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Board	Name	Date	Signature
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History:

Version Version	Date	Edit Motivation
00	24 january 2022	First issue



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Restorative Neurotechnologies quality policy is dedicated to all patients and end-users of our products and services. Restorative Neurotechnologies is dedicated to support professionals in neurorehabilitation clinical services, in order to improve the rehabilitation process for patients and healthcare professionals and also to improve quality of life of patients who suffer from cognitive deficit and neurological disease.

Cognitive deficits following neurological diseases are a dramatic social problem and often require long periods of rehabilitation to recover a good quality of life for the patients. Furthermore, many patients remain out of the rehabilitation process for the lack of sufficient neurorehabilitation services, with a consequent deterioration of residual cognitive abilities, a lack of autonomy, and the deterioration of the quality of life for the caregiver as well as for the patient. Rehabilitation services and health professionals have difficulty responding to the growing demand for neurorehabilitation related to the growing incidence of neurological deficits.

This document is dedicated to healthcare professionals who are potentially interested in our services and activities and other stakeholders, including our personnel, customers, clinical institutions, commercial partners, suppliers, patients' organizations and physicians' organizations, and competent Authorities.

Our quality policy is a declaration of intent concerning all aspects of our company life, emphasizing our focus on patients' safe and effective treatment through the

- Strict compliance to the highest **international standards** to ensure product safety
- Innovative approach to the provision of **clinical benefit** thanks to:
 - o Determination of patient status
 - o Provision of a cognitive training protocol



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Our cognitive training protocol is the result of more than 20 years of scientific research in the field of neurorehabilitation. Our research group has demonstrated that the integration of non-invasive neuromodulation of brain activity and serious games is effective for the rehabilitation of cognitive functions. The innovation brought by Restorative Neurotechnologies is related to non-invasive neuromodulation protocol: we have demonstrated that prismatic adaptation - a visuomotor task requiring the use of a special pair of glasses with prismatic lenses - is able to modulate brain activity with effects comparable to other non-invasive neuromodulation methods already used in clinical settings, without inducing magnetic fields or electrical currents that are characterized by several contraindications or side effects.

Our dedication to product development and customer satisfaction is shown through continuous research, planned to enhance the collection of clinical data through structured and evidence-based methods.

Our dedication is to maintain the company system efficacy with the aim to consolidate patient safety by means of clinical validation of our technological innovations and application of **software life cycle management principles** to the update of the product.

Our aspirations of continuous improvement are led by means of technological innovation via data-driven innovation.

The objective of the quality policy is to provide to the company personnel awareness on:

- Developing a product to improve the clinical outcome and quality of life of patients
- Ensuring that each product placed on the market complies with legal and regulatory requirements, including the Medical Devices Regulation.



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To ensure customer and end-user satisfaction, and to ensure patient safety and health the Company will:

- Certify the quality of our products and services in accordance with international standards.
- Strive to define and test new versions of our systems thanks to collection of clinical data in clinical trials, in the premarket and postmarket phase

The Board of Directors of Restorative Neurotechnologies intends to:

- Provide enough resources to the company system and ensure the continuous maintenance and update of infrastructure and personnel competence.
- Ensure that the Quality system is an integral part of company life.
- Promote the quality policy through measurable goals that are monitored over time.
- Define a risk-based surveillance and vigilance system, in compliance with European Regulations.
- Upgrade this policy as per requirements and as per the state of the art.

Date: 31/12/2021

Massimiliano Oliveri - CEO

Massimilieno Oliveni