March 22, 2019

MAYFAIR DEVELOPMENTS SAS

ØREBLUE®

HEARING INNOVATION

Press Release

CE MEDICAL Certification for a Device to Treat **HYPERACUSIS** and **TINNITUS**

The ØREBLUE® method is a personalized sound therapy developed by Natacha Chetritt-Bonneyrat, a qualified audioprosthetist. This method makes it possible, following a highly specific protocol, to completely and permanently eliminate symptoms of hyperacusis and to significantly reduce or even eradicate the symptoms of tinnitus, rather than artificially blocking them out. The excellent results of this therapy have led to the obtention of CE Medical Class IIa certification for the device associated with this method.

Natacha Chetritt-Bonneyrat, a visionary audioprosthetist

Originally from Nantes, Natacha Chetritt-Bonneyrat first studied audiophonology at Hôpital Edouard Herriot in Lyon under Professor Lionel Collet. Faced with the desperation of patients suffering from tinnitus whom she encountered at the hospital, she decided to devote her career to the subject. She then joined the faculty of Montpellier, where she earned a diploma in audioprosthesis. In the last twenty years, in parallel to her career as an audioprosthetist, she has conducted research into the mechanisms behind the symptoms of hyperacusis and tinnitus.

Her investigations led her to develop a unique therapeutic protocol that makes it possible to permanently eliminate the symptoms of hyperacusis and significantly reduce or even eliminate the symptoms of tinnitus.

ØREBLUE®, an acoustic and medical approach

The ØREBLUE® method is a personalized sound therapy designed to restore cortical organization.

The aim is to reduce hyperactive nervous system reactions (in the autonomic and limbic systems) in the case of tinnitus, and to increase the dynamic range of sound by increasing the plasticity of the subconscious neural networks stimulated in the case of hyperacusis.

It has been observed that the symptoms of tinnitus and hyperacusis provoke generalized states of hypervigilance in subjects, which lead to an aversive reflex, similar to the reflex that is triggered by any threat to well-being.

In such cases, the brain may attempt to filter or remove the subject from the stimulus identified as intrusive.

This is why, unlike therapies that use noise generators, the ØREBLUE® method uses music. One of the major advantages of this choice is to place the patient in a highly receptive state, which increases the acceptability of the treatment.

This audible tool is modified using a software program whose specially-developed algorithms apply acoustic filters tailored to the patient's medical and emotional hearing pattern, which means that each therapeutic program is both precise and fully personalized.

The ØREBLUE® method was developed thanks to the large volume of medical and acoustic data analyzed, and thanks to the development by a French engineering firm of an innovative digital device to process sound signals.

ØREBLUE® obtains CE Medical certification

The obtention of CE Medical certification serves as official recognition that the device used for the ØREBLUE® method meets, in treatments of hyperacusis and tinnitus, the highest safety and performance standards required for healthcare equipment, and guarantees that the risk-benefit balance has been clearly demonstrated.

This long, formal process was carried out by an independent certifying organization and culminated, after 17 months of testing and technical validation, in the obtention of the certification in March 2019 (certified by BSI with certificate number CE 667381).

It is officially registered with the ANSM (the French National Agency for the Safety of Medications and Healthcare Products).

Obtention of ISO 13485:2016 certification

In September 2017, Natacha Chetritt-Bonneyrat obtained ISO 13485:2016 certification* for her company Mayfair Developments in La Rochelle. The obtention of this certification was the first step in obtaining the recognition of the device used for the ØREBLUE® method.

To date, she is the first and only French audioprosthetist with this level of professional certification.

** ISO 13485 certification is an internationally recognized standard that sets requirements for quality management systems in the medical device sector. It was revised in March 2016.*

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Ms. Natacha CHETRITT-BONNEYRAT
18 QUAI SENAC DE MEILHAN - 17000 LA ROCHELLE - France
Tel. +33 (0)5 43 28 74 41
nbonneyrat@mayfair-developments.com
www.hearing-institute-of-resources.fr

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