

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 615889**
Issued To: **Neuromod Devices Limited**
Rainsford Street
Dublin
D08 R2YP
Ireland

In respect of:

The design and manufacture of nerve and auditory stimulation devices for the treatment of tinnitus.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-11-20**

Date: **2019-10-10**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 615889

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NBOG codes	Device Name	Intended purpose per IFU
Class IIa		
MD 1103	Lenire	The LENIRE device is intended to be used by tinnitus sufferers of at least 18 years of age to alleviate the symptoms of chronic, subjective tinnitus.
MD 1103	Tonguetip	The tonguetip device is an accessory to, and is intended to be used with, the LENIRE System.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 615889**
 Date: **2019-10-10**
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Date	Reference Number	Action
20 November 2014	8169771	First Issue.
12 October 2015	8418242	Change of address to Neuromod Devices Limited, NexusUCD, Belfield Office Park, Beech Hill Road, Clonskeagh, Dublin 4, Ireland.
4 November 2016	8633067	Removal of subcontractors M&M Qualtech Ltd and Molex Ireland Ltd.
26 April 2017	8728718	Change of the legal manufacturer's address from NexusUCD, Belfield Office Park, Beech Hill Road Clonskeagh, Dublin 4 to Digital Hub, Unit J The Digital Court, Rainsford St, Dublin 8.
20 December 2018	8855925	Traceable to NB 0086.
01 August 2019	9767345	Modify address on the certificate from "Neuromod Devices Limited, Digital Hub, Unit J, The Digital Court, Rainsford St, DUBLIN 8, Ireland" to "Neuromod Devices Limited, Rainsford Street, Dublin 8, D08R2YP, Ireland".
Current	9732563	Certificate renewal

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