By Royal Charter

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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Supplementary Information to CE 615889

Issued To:

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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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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 615889**
Date:	**2019-10-10**
Issued To:	**Neuromod Devices Limited** **Rainsford Street** **Dublin** **D08 R2YP** **Ireland**

Subcontractor:	**Service(s) supplied**
Medisize Ireland Ltd. High Road Letterkenny Co. Donegal Ireland	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 615889**
Date: **2019-10-10**
Issued To: **Neuromod Devices Limited**
Rainsford Street
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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".
10 October 2019	9732563	Certificate renewal
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
10 June 2021	3450428	Addition of critical subcontractor Medisize Ireland Ltd., High Road, Letterkenny, Co. Donegal, Ireland.

Inspiring trust for a more resilient world.

10 June 2021

Neuromod Devices Limited
Rainsford Street
Dublin
D08 R2YP
Ireland

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 615889	93/42/EEC Annex II excluding Section 4	3450428	Addition of critical subcontractor Medisize Ireland Ltd., High Road, Letterkenny, Co. Donegal, Ireland

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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