By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 593638**

Issued To: **Nuraleve Inc. also operating as**
NorDocs technologies
888 Broadview Ave.
Ottawa
Ontario
K2A 2M5
Canada

In respect of:

The design and manufacture of Transcranial Direct Current Stimulation (tDCS) devices.

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: **2015-08-10** Date: **2020-08-06** Expiry Date: **2024-05-26**

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Supplementary Information to CE 593638

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1103	SmartStim Model 1000 Transcranial Direct Current Stimulation Device	---

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 593638**

Date: **2020-08-06**

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Date	Reference Number	Action
10 August 2015	7917951	Initial Issue
12 March 2019	8849722	Reissue due to amendment to the legal manufacturer address.
18 March 2019	8861682	Traceable to NB 0086.
06 August 2020	9736678	Certificate Renewal
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
22 May 2024	30000316	Change in legal manufacturer address from "888 Broadview Avenue, Ottawa, ON K2A 2M5" to "909 Rex Avenue, Ottawa, ON K2A 2P6". Addition of manufacturer site located at address "Dymon Storage, Unit # A457, 1554 Carling Ave, Ottawa, ON, Canada, K1Z 7M4". Removal of subcontractor page.

Inspiring trust for a more resilient world.

22 May 2024

Nuraleve Inc. also operating as
NorDocs technologies
909 Rex Avenue
Ottawa
Ontario
K2A 2P6
Canada

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 593638	93/42/EEC Annex II excluding Section 4	30000316	Change in legal manufacturer address from "888 Broadview Avenue, Ottawa, ON K2A 2M5" to "909 Rex Avenue, Ottawa, ON K2A 2P6". Addition of manufacturer site located at address "Dymon Storage, Unit # A457, 1554 Carling Ave, Ottawa, ON, Canada, K1Z 7M4". Removal of subcontractor page.

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,

Graeme Tunbridge
Senior Vice President, Medical Devices