

# 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):



Albert Roossien, Regulatory Lead

First Issued: **2015-08-10**

Date: **2019-03-18**

Expiry Date: **2020-08-09**

...making excellence a habit.™

Page 1 of 2

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.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 593638

Issued To:

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

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

First Issued: **2015-08-10**

Date: **2019-03-18**

Expiry Date: **2020-08-09**

...making excellence a habit.™

Page 2 of 2

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.

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

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

## List of Significant Subcontractors

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

Certificate No: **CE 593638**  
Date: **2019-03-18**  
Issued To: **Nuraleve Inc. also operating as  
NorDocs technologies  
888 Broadview Ave.  
Ottawa  
Ontario  
K2A 2M5  
Canada**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Obelis SA Bd Général Wahis, 53 Brussels 1030 Belgium	<b>EU Representative</b>
RMF Design & Manufacturing Inc. 5675 Timberlea Blvd Mississauga Ontario L4W 2S4 Canada	<b>Manufacture</b>

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System Certificate History

**Certificate No:** CE 593638  
**Date:** 2019-03-18  
**Issued To:** Nuraleve Inc. also operating as  
 NorDocs technologies  
 888 Broadview Ave.  
 Ottawa  
 Ontario  
 K2A 2M5  
 Canada

Date	Reference Number	Action
10 August 2015	7917951	Initial Issue
12 March 2019	8849722	Reissue due to amendment to the legal manufacturer address.
Current	8861682	Traceable to NB 0086.

...making excellence a habit.™

Page 1 of 1

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.

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.