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.™

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
Class IIa		
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.™

By Royal Charter

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**

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

...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.