

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
1-2280 Carling Ave
Ottawa
Ontario
K2B 7G1
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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **10 August 2015**

Date: **10 August 2015**

Expiry Date: **09 August 2020**

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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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List of Significant Subcontractors

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

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Subcontractor:

Service(s) supplied

Obelis SA
Boulevard General Wahis 53
Brussels
1030
Belgium

EU Representative

RMF Design & Manufacturing Inc.
5675 Timberlea Blvd
Mississauga
Ontario
L4W 2S4
Canada

Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

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| Date | Reference Number | Action |
|----------------|------------------|---------------|
| 10 August 2015 | 7917951 | Initial Issue |

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