By Royal Charter

# EC Certificate - Full Quality Assurance System

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

**No.** **CE 579042**

Issued To: **NR Sign Inc.**
**3771 Jacombs Road, Unit 330**
**Richmond**
**British Columbia**
**V6V 2L9**
**Canada**

In respect of:

**Design and manufacture of electroencephalography (EEG, LTM) and electromyography (EMG/NCV/EP) diagnostic systems.**

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: **2012-06-25** Date: **2020-03-27** Expiry Date: **2022-06-24**

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# EC Certificate - Full Quality Assurance System

**Supplementary Information to CE 579042**

Issued To:

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| NBOG code(s) | Device description | Intended Purpose |
|---|---|---|
| **Class IIa** | | |
| MD 1301 | Electroencephalogram (EEG, LTM) Active Monitoring Device | N/A |
| MD 1301 | Electromyogram (EMG/NCV/EP) Active Monitoring Device | N/A |

First Issued: **2012-06-25** Date: **2020-03-27** Expiry Date: **2022-06-24**

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# List of Significant Subcontractors

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

| | |
|---|---|
| Certificate No: | **CE 579042** |
| Date: | **2020-03-27** |
| Issued To: | **NR Sign Inc.**<br>**3771 Jacombs Road, Unit 330**<br>**Richmond**<br>**British Columbia**<br>**V6V 2L9**<br>**Canada** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Preissler Medintechnik<br>Augsburger Strasse 75<br>D-87600 Kaufbeuren<br>Germany | **EU Representative** |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 579042**

Date: **2020-03-27**

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**Richmond**
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**V6V 2L9**
**Canada**

| Date | Reference Number | Action |
|---|---|---|
| 25 June 2012 | 7731475 | First issue. |
| 13 November 2015 | 8431572 | Change of certificate address<br>Change of scope to Design and manufacture of electroencephalography (EEG, LTM) and electromyography (EMG/NCV/EP) diagnostic systems. |
| 16 June 2017 | 8727180 | Certificate Renewal. |
| 10 April 2019 | 7782375 | Traceable to NB 0086. |
| Current | 3104583 | Re-issued with change of Legal Manufacturer's address and addition of Device Table. |