

# 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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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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## Supplementary Information to CE 579042

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NBOG code(s)	Device description	Intended Purpose
<b>Class IIa</b>		
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**

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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.

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## List of Significant Subcontractors

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

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**Canada**

**Subcontractor:**

**Service(s) supplied**

Preissler Medintechnik  
Augsburger Strasse 75  
D-87600 Kaufbeuren  
Germany

**EU Representative**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 579042**  
 Date: **2020-03-27**  
 Issued To: **NR Sign Inc.**  
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**Canada**

Date	Reference Number	Action
25 June 2012	7731475	First issue.
13 November 2015	8431572	Change of certificate address 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.