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Natus Neurology Incorporated
3150 Pleasant View Road
Middleton, Wisconsin 53562 USA

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC as Amended by 2007/47/EC

CE 0086

Declaration Number:	**QMS-002131 rev 01**	*[DCO-14907]*
Product Name:	**Natus Neurology Diagnostic and Monitoring Devices - Class IIb**	
Product Model Number:	**see Annex: Product List**	
Description:	**Electroencephalography (EEG), Electromyography (EMG), Evoked Potential (EP) and Electronystagmography (ENG) Diagnostic and Monitoring Devices**	

Natus Neurology Incorporated hereby declares that the above medical devices which bear the CE Mark are in conformity with the applicable requirements of EC Directive 93/42/EEC with amendments up to as enforced in the national laws of the European Union member states.

Classification/Rule:	**Class IIb, by Annex IX, Rule 10**
Conformity Assessment Route:	**Annex II**

This declaration is based on Certification of a full Quality Assurance System and compliance to the Medical Device Directive.

Certificate No.:	**CE 592232**
Issued by:	**BSI - British Standards Institution**
Certificate Issue Date:	**12 Feb 2013**

Additionally: Natus hereby declares, under its sole responsibility as Legal Manufacturer and not evaluated by the Notified Body listed above, that the product specified on this Declaration of Conformity is in conformity with Council Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. It has been demonstrated that the requirements specified in Article 4 of directive 2011/65/EU have been met.

EU Authorized Representative: Natus Manufacturing Limited.
IDA Business Park
Gort, Co. Galway
Ireland

Signature: Glen Hermanson **Date:** 3 Mar 2016

Name: Glen Hermanson

Title: Regulatory Affairs Manager - Mfg.

Digitally signed by Grabazei Alexandru
Date: 2020.05.08 15:55:13 EEST
Reason: MoldSign Signature
Location: Moldova

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Annex to the Declaration of Conformity

PRODUCT LIST

ELECTROENCEPHALOGRAPHY, ELECTROMYOGRAPHY, EVOKED POTENTIAL AND ELECTRONYSTAGMOGRAPHY DIAGNOSTIC, MONITORING DEVICES PRODUCT FAMILY - Class IIb

This product list belongs to the Declaration of Conformity identified by Electroencephalography, Electromyography, Evoked Potential and Electronystagmography Diagnostic and Monitoring Devices Product Family - Class IIb and specifies the CE marked products concerned that Natus Neurology Incorporated intends to distribute in conformity with the provisions of the Council Directives 93/42/EEC and 2011/656/EU. The following list identifies the products by name and type and by serial number or beginning shipping date.

Product name	Beginning Serial Number or Shipment After Date
Endeavor CR	21July 2014
VikingQuest	21July 2014
Nicolet EDX	21July 2014
UltraPro S100	21July 2014
Nicolet Cortical Stimulator *(Nicolet CS)*	21July 2014
Nicolet EEG *(NicoletOne)*	21July 2014
Nicolet Monitor	21July 2014
Nicolet LTM	21July 2014
ACCESSORIES:	
1. Nicolet EEG Wireless 32A, Nicolet EEG Wireless 64A	21July 2014
2. Amplifiers EEG C64, Amplifiers EEG C128 (2xC64)	21July 2014
3. Amplifiers EEG (V32 & V44)	21July 2014
4. Amplifier EMG/EP	21July 2014
5. Auditory Stimulators	21July 2014
6. Bone Vibrator	21July 2014
7. Electrical Stimulator -'403' series	21July 2014
8. Footswitch	21July 2014
9. Headbox	21July 2014
10. 'S' Series Stimulus probe	21July 2014
11. Stimulus Switching -IES series, etc.	21July 2014
12. Stimulus Probe Head	21July 2014
13. RS10 and WR50 Stimulus probes & Heads	21July 2014
14. Advanced Stimulus Probe	21July 2014
15. Visual Stimulators '2015', Photic, Goggles	21July 2014
16. CS Control Unit, CS Switching Unit	21July 2014
17. Software NicoletOne, Endeavour, Synergy & Viking	21July 2014
18. XPOD Pulse Oximeter Module	08 Oct. 2014

Issued by:
Natus Neurology Incorporated *aka: Natus Medical Incorporated*
3150 Pleasant View Road
Middleton, Wisconsin 53562 USA

Signature: Glen Hermanson Date: 3 Mar 2016
Name: Glen Hermanson
Title: Regulatory Affairs Manager - Mfg.