

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



**Declaration Number:** QMS-002120 rev 01 [DCO-10528]  
**Product Name:** Natus Neurology Accessory Devices Product Family - Class I  
**Product Model Number:** see Annex: Product List  
**Description:** Accessory and Consumable 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 I, by Annex IX, Rule 1  
**Conformity Assessment Route:** Annex VII

This declaration is based on Certificate of Registration of a Quality Management System to:

**Quality standard:** ISO 13485:2003  
**Certificate No.:** FM 602280  
**Issued by:** BSI - British Standards Institution  
**Certificate Issue Date:** 08 Nov 2013

Additionally: Natus hereby declares, under its sole responsibility as Legal Manufacturer 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:** Shane T. Sawall **date:** 1 Aug 2016  
**Name:** Shane T. Sawall  
**Title:** Regulatory Affairs Manager

attached: Annex: Product List - Natus Neurology Accessory Devices Product Family - Class I

**Annex to the Declaration of Conformity**

**PRODUCT LIST**

**Natus Neurology Accessory Devices Product Family - Class I**

This product list belongs to the Declaration of Conformity identified by Accessory Devices Product Family - Class I 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 2011/65/EU. The following list identifies the products by type and by serial number or beginning shipping date.

<u>Accessory Device Product Category Name</u>	<u>Beginning Shipped After Date</u>
Accessories, Support	21 July 2014
Electrodes, Cables, Clips, Adapters	21 July 2014
Electrode to Skin Interface	21 July 2014
Electrodes, Surface	21 July 2014
Skin Contacting	21 July 2014
Transducers	21 July 2014
Review System & Software	21 July 2014

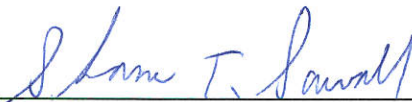
Issued by:  
Natus Neurology Incorporated  
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