

Natus Europe GmbH Robert-Koch-Str. 1 82152 Planega Germany

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

**Declaration Number:** 

DOC-011892

Product Name:

**EEG Surface Electrodes** 

Product Model Number: 505011, 505012, 505013, 505014, 505015, 505016, 505017,

505018, 505201, 505203, 505207, 505209, 505210, 505212,

505213, 505220, 505222, 505223, 515040, 515041, 515045

**Description:** 

**EEG Surface Electrodes** 

Natus Medical 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 IX

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

Certificate No.:

HD 60089982 0001

Issued by:

TÜV Rheinland LGA Products GmbH

Date:

2013-12-23

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.

Signature: per pro

Séamus O'Connor - Quality Manager

date 31 Jul 2014