

EC Certificate - Full Quality Assurance System

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

No.

CE 541606

Issued To:

**Natus Medical Incorporated
5900 First Avenue South
Seattle
Washington
98108
USA**

In respect of:

The design, development and manufacture of infant phototherapy systems, products for the quantitative assessment and rehabilitation of balance disorders, evoked response hearing screeners and otoacoustic audiometers.

Those aspects of Annex II related to the metrology of products for the quantitative assessment and rehabilitation of balance disorders.

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2008-10-06**

Date: **2018-11-08**

Expiry Date: **2021-06-11**

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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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List of Significant Subcontractors

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

Certificate No: **CE 541606**
 Date: **2018-11-08**
 Issued To: **Natus Medical Incorporated**
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Subcontractor:	Service(s) supplied
Beyonics International Pte. Ltd 51 Marsiling Road 739114 Singapore	Manufacture
Creation Technologies LP 8977-8999 Fraserton Court Burnaby British Columbia V5J 5H8 Canada	Manufacture
Excelitas Technologies LED Solutions Inc 160 E. Marquardt Dr. Wheeling, IL 60090 USA	Manufacture

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Subcontractor:

Service(s) supplied

Katecho Inc
 4020 Gannett Avenue
 Des Moines
 Iowa
 50321
 USA

Manufacture

Natus Manufacturing Limited
 IDA Business Park
 Gort
 Co. Galway
 Ireland

EU Representative

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Certificate History

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Date	Reference Number	Action
06 October 2008	7275816	First Issue Transfer from another Notified Body
07 July 2009	7389325	<p>Certificate re-issue due to the scope extension to include 'infant phototherapy systems and oxygen hoods'.</p> <p>The following significant sub-contractors were included in the list of significant sub-contractors:</p> <p>Farstar (Wuxi) Medical Equipment Co., Ltd., (No. 7, Chang Jiang Rd.), Lot 402, 2Dd, Area, Wuxi Science & Tech Park, Wuxi, Jiangsu, China' for the activity of manufacture.</p> <p>'Creation Technologies LP, Burnaby Business Unit, 102 – 8977 Fraserton Court, Burnaby, British Columbia V5J 5G1, Canada' for the activity of manufacture.</p> <p>'Natus Europe GmbH, Bärmannstrasse 38, 81245 München, Germany' for the activity of EC Representative.</p>

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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Date	Reference Number	Action
02 June 2011	7686469	<p>Certificate renewal</p> <p>The following significant subcontractors for manufacture have been added to the certificate:</p> <p>Excelitas Technologies LED Solutions Inc, 160 E. Marquardt Dr, Wheeling, IL 60090,USA</p> <p>Measurement Specialties, Inc, 2670 Indian Ripple Road, Dayton, OH 45440, USA</p> <p>The Electrode Store, 159 West Mason, Buckley, Washington, 98321, USA</p>
01 February 2013	7943275	<p>Change of EU Representative address from 'Bärmannstrasse 38, D-91245 München, Germany' to 'Robert-Koch-Str.1, 82152 Planegg, Germany'</p>

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Date	Reference Number	Action
09 April 2014	8014834	<p>Removal of significant sub-contractors 'Measurement Specialities, Inc' for the activity of manufacture.</p> <p>Addition of significant sub-contractors 'Katecho, Inc' for the activity of manufacture.</p> <p>Scope expanded to include "products for the quantitative assessment and rehabilitation of balance disorders, electroencephalograph systems, evoked response systems, otoacoustic emissions systems, hearing screeners and audiometers; those aspects of Annex II related to metrology of products for the quantitative assessment and rehabilitation of balance disorders".</p> <p>Addition of subcontractor Beyonics International Pte Ltd.</p>

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01 June 2016	8534671	Certificate renewal. Scope reduced by the removal of 'cerebral function monitors, therapeutic neonatal head cooling devices' and 'electroencephalograph systems'. Scope clarification with respect to hearing screeners and audiometers. Creation Technologies address changed from '102 - 8977 Fraserton Court, Burnaby, British Columbia' to '8977-8999 Fraserton Court Burnaby, British Columbia, V5J 5H8, Canada'. Change of EU Representative to Natus Manufacturing Limited, IDA Business Park, Gort, Galway, Ireland.
13 April 2017	8711277	Change of EU Representative from "Natus Manufacturing Limited" to "Natus Europe GmbH, Robert-Koch-Str.1, 82152 Planegg Germany". Removal of significant sub-contractors 'The Electrode Store' for the activity of manufacture.

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Current	8939286	Change in EU rep to Natus Manufacturing Ltd Update is scope to remove oxygen hoods Removal of Subcontractor Farstar Change in address for subcontractor Beyonics
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