By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 01995**

Issued To: **Natus Medical Incorporated**
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville
Ontario
L6H 5S1
Canada

In respect of:

The design, development, manufacture and installation of: systems for diagnosis and monitoring using electrophysiological signals; photic and cortical stimulators.

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):

Albert Roossien, Regulatory Lead

First Issued: **1998-07-07** Date: **2019-02-12** Expiry Date: **2023-07-06**

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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.

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

List of Significant Subcontractors

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

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Subcontractor:	**Service(s) supplied**
Creation Technologies 6820 Creditview Road Mississauga Ontario L5N OA9 Canada	**Manufacture**
Ducommun LaBarge Technologies, Inc. 2222 East Pensar Drive Appleton Wisconsin 54911 USA	**Manufacture**
Natus Manufacturing Limited IDA Business Park Gort Co. Galway Ireland	**EU Representative** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Natus Neurology Incorporated 3150 Pleasant View Road Middleton Wisconsin 53562 USA	**Manufacture**

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Date	Reference Number	Action
07 July 1998	-	First Issued
31 August 1999	-	Extension to scope, Change of address
24 September 1999	-	Extension to scope
23 November 2000	-	Extension to scope
14 October 2003	-	Five year renewal, reissue in new format
30 April 2008	7199407	Certificate renewal
16 December 2008	7292967	Change of company name from Excel-Tech Ltd. (XL TEK) to Natus Medical Incorporated, DBA Excel-Tech Ltd. (XL TEK)
25 November 2011	7635138	Re-issue due to addition of significant subcontractors as below: - Braintronics BV, The Netherlands - Manufacture - EB Neuro S.r.P Italy, - Manufacture - Creation Technologies, Canada – Manufacture - Natus Europe Gmbh (Planegg), Germany - EU Rep. and Manufacture
01 July 2013	7972894	Certificate renewal

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Date	Reference Number	Action
20 December 2013	8091741	Addition of subcontractor Astro-Med Inc, Greenwich Ave, W.Warwick, RI. Extension and scope clarification was 'The design, development, manufacture and installation of systems for the diagnosis and monitoring of electrophysiological signals' now 'The design, development, manufacture and installation of: systems for diagnosis and monitoring using electrophysiological signals; photic and cortical stimulators.'
04 November 2014	8244952	Addition of significant subcontractor Ducommun LaBarge Technologies, Inc. 2222 East Pensar Drive, Appleton. Wisconsin, 54911, USA for manufacture.
18 March 2016	8471779	Removal of significant subcontractors Astro-Med Inc located in Rhode Island, Braintronis BV located in The Netherlands and EB Neuro SpA located in Italy.
04 November 2016	8623295	Removal of significant subcontractor Natus Europe GmbH. Addition of Natus Manufacturing Limited, IDA Business Park, Gort, Co. Galway, Ireland as EU Representative.

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Date	Reference Number	Action
26 April 2017	8728517	Addition of Subcontractor Natus Neurology Incorporated for manufacture.
02 July 2018	8995712	Renewal Addition of manufacturing activities to Natus- Ireland
Current	7781690	Traceable to NB 0086.

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