Natus Medical Incorporated
DBA Excel-Tech Ltd. (Xltek)
2568 Bristol Circle
Oakville, Ontario, Canada L6H 5S1
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**www.natus.com**

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

CE 2797

**Declaration Number:** DOC-048016 Rev 03
**Product Name:** MPR
**GMDN Code:** 33843
**Product Model Number:**

| *Product Description* | *Model Numbers* |
|---|---|
| **Embletta MPR** | 2003010 |
| **Embletta MPR PG** | 2003011 |
| **Tx Proxy Unit** | 2013030 |
| **ST and ST+ Proxy Units** | 2013031, 2013032 |
| **Oximeter XPOD LP MPR** | 011291 |

**Description:** MPR

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 2007/47/EEC as enforced in the national laws of the European Union member states.

**Classification/Rule:** Class IIa, by Annex IX, Rule 10
**Conformity Assessment Route:** Council Directive 93/42/EEC as amended by 2007/47/EC, Annex II, section 3.2

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

**Certificate No.:** CE 01995
**Issued by:** **British Standards Institution (No 2797),**
Say Building, John M. Keynesplein 9,
1066 EP Amsterdam,
Netherlands
**Date:** 21 May 2021

**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.**

**This declaration of conformity is valid from** – May 26, 2021

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

**Signature:** _____ **date** May25,2021
Sanjay Mehta (Director Global Regulatory Affairs, QARA)

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# 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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1998-07-07** Date: **2020-05-04** Expiry Date: **2023-07-06**

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# EC Certificate - Full Quality Assurance System

**Supplementary Information to CE 01995**

Issued To:

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

| Number | Device Description | Intended purpose |
|---|---|---|
| **Class IIa** | | |
| MD 1302 | Electroencephalograph (EEG):<br>Neuroworks Software<br>EEG32U<br>EMU40EX with Natus Base Olympic Brainz monitor | N/A - Class IIa |
| MD 1302 | Electroencephalograph (EEG) & Polysomnography (PSG – Sleep Study):<br>Trex HD<br>Quantum Amplifier<br>SleepWorks Software<br>"Natus Brain Monitor EMBLA Dx Series" | |

First Issued: **1998-07-07** Date: **2020-05-04** Expiry Date: **2023-07-06**

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# EC Certificate - Full Quality Assurance System

**Supplementary Information to CE 01995**

Issued To:

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**2568 Bristol Circle**
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**Ontario**
**L6H 5S1**
**Canada**

| Number | Device Description | Intended purpose |
|---|---|---|
| **Class IIa** | | |
| MD 1302 | Polysomnography (PSG – Sleep Study):<br>Embletta MPR<br>Embletta MPG PG<br>TX Proxy Unit<br>Xacttrace belt<br>RemLogic<br>RemLogic E<br>Embla Breathsensors<br>ST proxy<br>ST+ proxy | |
| MD 1103 | Evoked Potential (EP):<br>Protektor 32 | |

First Issued: **1998-07-07** Date: **2020-05-04** Expiry Date: **2023-07-06**

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# EC Certificate - Full Quality Assurance System

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:

| | |
|---|---|
| Certificate No: | **CE 01995** |
| Date: | **2020-05-04** |
| Issued To: | **Natus Medical Incorporated**<br>**DBA Excel-Tech Ltd. (XLTEK)**<br>**2568 Bristol Circle**<br>**Oakville**<br>**Ontario**<br>**L6H 5S1**<br>**Canada** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| ASIA CONNECTION CO., LTD.<br>16F-1<br>No. 16 Jian Ba Road<br>Chung Ho District<br>New Taipei City<br>23511<br>Taiwan | **Manufacture** |
| Cogent Technology Limited<br>Dock Lane<br>Melton<br>Woodbridge<br>IP12 1PE<br>United Kingdom | **Manufacture** |
| Creation Technologies<br>6820 Creditview Road<br>Mississauga<br>Ontario L5N OA9<br>Canada | **Manufacture** |

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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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# EC Certificate - Full Quality Assurance System

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

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

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Ducommun LaBarge Technologies, Inc.<br>2222 East Pensar Drive<br>Appleton<br>Wisconsin 54911<br>USA | **Manufacture** |
| Jiangyin SINBON Electronics Co., Ltd.<br>No. 288 Chengjiang Middle Road<br>Economic and Development Zone<br>Jiangyin City<br>Jiangsu Province, 214434<br>P.R. China | **Manufacture** |
| Natus Manufacturing Limited<br>IDA Business Park<br>Gort<br>Co. Galway<br>Ireland | **EU Representative**<br>**Manufacture** |

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# EC Certificate - Full Quality Assurance System

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

# List of Significant Subcontractors

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| Date: | **2020-05-04** |
| Issued To: | **Natus Medical Incorporated**<br>**DBA Excel-Tech Ltd. (XLTEK)**<br>**2568 Bristol Circle**<br>**Oakville**<br>**Ontario**<br>**L6H 5S1**<br>**Canada** |

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

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01995**

Date: **2020-05-04**

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

| 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:<br>- Braintronics BV, The Netherlands - Manufacture<br>- EB Neuro S.r.P Italy, - Manufacture<br>- Creation Technologies, Canada – Manufacture<br>- Natus Europe Gmbh (Planegg), Germany - EU Rep. and Manufacture |
| 01 July 2013 | 7972894 | Certificate renewal |

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# EC Certificate - Full Quality Assurance System Certificate History

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**Ontario**
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**Canada**

| Date | Reference Number | Action |
|---|---|---|
| 20 December 2013 | 8091741 | Addition of subcontractor Astro-Med Inc, Greenwich Ave, W.Warwick, RI.<br>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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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01995**

Date: **2020-05-04**

Issued To: **Natus Medical Incorporated**
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**Canada**

| Date | Reference Number | Action |
|---|---|---|
| 26 April 2017 | 8728517 | Addition of Subcontractor Natus Neurology Incorporated for manufacture. |
| 02 July 2018 | 8995712 | Renewal<br>Addition of manufacturing activities to Natus- Ireland |
| 12 February 2019 | 7781690 | Traceable to NB 0086. |
| Current | 3168650 | Polysomnography (PSG - Sleep Study) devices added to the certificate under existing scope.<br>Following critical subcontractors added:<br>- Cogent Technology Limited<br>- Jaingyin SINBON Electronics Co., Ltd.<br>- Asia Connection Co., Ltd.,<br>Device table added for completion. |