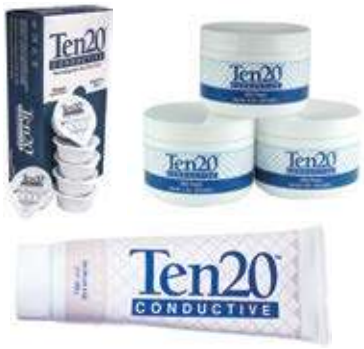
Electrode Creams, Pastes, Gels

Grass® EC2+® Electrode Cream

- Hardens and holds electrodes securely in place even during LTM for consistently clear signals
- Sets quickly to maintain electrode position
- Isotonic formula is gentle on the skin
- Remove by softening with a wet cloth. No harsh solvents required

Part Number	Type	Size	Quantity
EC2+*	Electroconductive Cream	3.5oz (100g) tube	10/box

*Not for sale in US & Canada



Ten20® Conductive Paste

- Balance of adhesiveness and conductivity
- Washable and non-drying; easy clean-up

Part Number	Type	Size	Quantity
026525	Ten20 Electrode Paste	Single-Use Cups 0.5oz (15g)	24/pkg
024066	Ten20 Electrode Paste	2oz (50g) jar	3/pkg
1411003	Ten20 Electrode Paste	4oz (114g) jar	3/pkg
016-703700	Ten20 Electrode Paste	8oz (228g) jar	3/pkg
122-736000	Ten20 Electrode Paste	4oz (114g) tube	3/pkg

SYNAPSE Conductive Electrode Cream

- Convenient application
- Non-staining to skin or clothing
- Rapid and easy clean-up

Part Number	Type	Size	Quantity
016-703800	Synapse Conductive Electrode Cream	5oz (140g) bottle	1/pkg

Grass® EC3® Conductive Adhesive Gel

- Conductive immediately – no waiting period
- Water soluble; easily removable; non-staining
- Non-flammable; no solvent odor or fumes
- Eliminates tape and tape irritation
- Bacteriostatic

Part Number	Type	Size	Quantity
EC3	Conductive Adhesive Gel	1.76oz (50g) tube	12/box

TENSIVE® Conductive Adhesive Gel

- Eliminates tape and tape irritation
- Immediately conductive
- Water soluble; easily remove with water

Part Number	Type	Size	Quantity
016-401600	Tensive Conductive Adhesive Gel	1.76oz (50g) tube	1/pkg
026040	Tensive Conductive Adhesive Gel	1.76oz (50g) tube	12/pkg

SIGNACREME® Electrode Cream

- Highly conductive cream electrolyte for use in electro-medical procedures
- Cosmetic quality, pleasing to patients
- Non-irritating, bacteriostatic

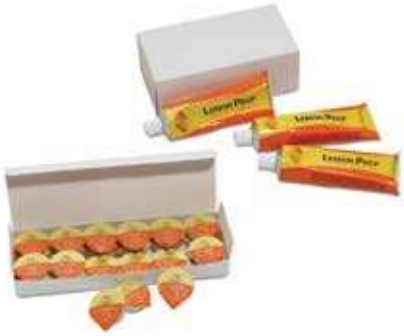
Part Number	Type	Size	Quantity
101086	Signacreme	5oz (142g) bottle	1/pkg

Skin Preps

NuPrep® Skin Prep Gel

- Used to reduce skin impedance for improved tracings
- Mild abrasive formula improves conductivity
- Helps achieve maximum efficiency with equipment

Part Number	Type	Size	Quantity
024065	NuPrep Skin Prep	1oz (25g) tube	6/pkg
122-736100	NuPrep Skin Prep	4oz (114g) tube	3/pkg



LemonPrep™ Abrasive Skin Prepping Lotion

- Balanced pH formula to minimize impedance
- Includes aloe vera to condition patient's skin
- Lemon scent

Part Number	Type	Size	Quantity
016-401000	LemonPrep Skin Prep	4oz (113g) tube	3/pkg
016-403300	LemonPrep Skin Prep Single Patient Cups	0.35oz (9.9g) cups	24/pkg

Waveprep® Mildly Abrasive Skin Prep

- Dye free, mildly abrasive, reduces skin impedance
- Single use cups reduce risk of cross-contamination

Part Number	Type	Size	Quantity
016-402900*	Waveprep Skin Prep Single Patient Cups	0.3oz (8.5g) cups	24/pkg

*US only

016-703200

016-703000

Electrode Prep Pads & Alcohol Pads

- Use to cleanse electrode site and lower impedance
- Prep pad is formulated with pumice
- Both pads are saturated with 70% isopropyl alcohol

Part Number	Type	Size	Quantity
016-703200*	Electrode Prep Pad	1.25" (3.18cm) x 2.5" (6.35cm)	100/pkg
016-703000	Alcohol Pads	1.25" (3.18cm) x 2.5" (6.35cm)	200/pkg

*Not for sale in Europe

Uni-Patch™ Pre-TENS Skin Prep Wipes

- Pre-treatment skin wipe cleans, disinfects, and leaves a coating to shield the skin from adhesives and possible irritation
- Increases conductivity and prevents body oils from being absorbed into the electrode gel

Part Number	Type	Size	Quantity
444020*	Skin Prep Pad	1.25" (3.18cm) x 2.5" (6.35cm)	50/pkg

*US only

3M™ One Step Red Dot™ Skin Prep Abrader Tape

- Abrasive tape works just like gel preps without the mess
- Adhesive on one side and abrasive on the other

Part Number	Type	Size	Quantity
016-400000	Skin Prep Tape	196" (5m) roll	1/pkg

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-07-07** Date: **2018-07-02** 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:	**2018-07-02**
Issued To:	**Natus Medical Incorporated** **DBA Excel-Tech Ltd. (XLTEK)** **2568 Bristol Circle** **Oakville** **Ontario** **L6H 5S1** **Canada**

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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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:	**2018-07-02**
Issued To:	**Natus Medical Incorporated** **DBA Excel-Tech Ltd. (XLTEK)** **2568 Bristol Circle** **Oakville** **Ontario** **L6H 5S1** **Canada**

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

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01995**

Date: **2018-07-02**

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: - 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

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01995**

Date: **2018-07-02**

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

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.
26 April 2017	8728517	Addition of Subcontractor Natus Neurology Incorporated for manufacture.
Current	8995712	Renewal Addition of manufacturing activities to Natus- Ireland

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EC Certificate - Full Quality Assurance System

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

No. **CE 592232**

Issued To: **Natus Neurology Incorporated**
3150 Pleasant View Road
Middleton
Wisconsin
53562
USA

In respect of:

Design and manufacture of Electro-Neurophysiologic Diagnostic and Monitoring Devices and Sterile and Non-Sterile Invasive Electrodes.

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: **2013-02-12** Date: **2018-06-29** Expiry Date: **2023-07-01**

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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 592232**
Date:	**2018-06-29**
Issued To:	**Natus Neurology Incorporated** **3150 Pleasant View Road** **Middleton** **Wisconsin** **53562** **USA**

Subcontractor:	**Service(s) supplied**
Ad-Tech Medical Instrument Corp. 400 West Oakview Parkway Oak Creek Wisconsin 53154 USA	**Manufacture**
Chalgren Enterprises, Inc 380 Tomkins Court Gilroy California 95020 USA	**Manufacture**
Ducommun LaBarge Technologies, Inc. 2222 East Pensar Drive Appleton Wisconsin 54911 USA	**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

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

Certificate No:	**CE 592232**
Date:	**2018-06-29**
Issued To:	**Natus Neurology Incorporated** **3150 Pleasant View Road** **Middleton** **Wisconsin** **53562** **USA**

Subcontractor:	**Service(s) supplied**
Natus Manufacturing Limited IDA Business Park Gort Co. Galway Ireland	**EU Representative** **Manufacture**
Paul E. Danchell A/S Lyngvej 8 Jyderup 4450 Denmark	**Manufacture**
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers B-4800 Belgium	**ETO Sterilization**

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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 592232**
Date:	**2018-06-29**
Issued To:	**Natus Neurology Incorporated** **3150 Pleasant View Road** **Middleton** **Wisconsin** **53562** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 2311 Lincoln Avenue Hayward California 94545 USA	**Gamma Sterilization**
Sterigenics US, LLC 7775 South Quincy Street Willowbrook Illinois 60527 USA	**ETO Sterilization**
Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 592232**

Date: **2018-06-29**

Issued To: **Natus Neurology Incorporated**
3150 Pleasant View Road
Middleton
Wisconsin
53562
USA

Date	Reference Number	Action
12 February 2013	7909188	Transfer from another Notified Body. The legal manufacturer, Natus Neurology Incorporated, is also known as Natus Medical Incorporated, CareFusion 209, Inc., VIASYS NeuroCare, VIA SYS Healthcare, Nicolet Biomedical, Nicolet Vascular
18 June 2013	7999455	Certificate renewal, and removal of Jabil Circuit Inc as significant subcontractor.
17 December 2013	8030396	Reissue due to change of company address from '1850 Deming Way, Middleton, WI 53562, USA' to '3150 Pleasant View Road, Middleton, WI 53562, USA' Addition of, 'Natus Neurology Incorporated, 1850 Deming Way, Middleton, Wisconsin, 53562, USA', for services of Design, Manufacture, Control of Sterilization and Regulatory Compliance. Change of subcontractor name from 'Natus Nicolet Ireland Ltd also trading as CareFusion Manufacturing Ireland 241 Limited' to 'Natus Manufacturing Limited'.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 592232**

Date: **2018-06-29**

Issued To: **Natus Neurology Incorporated**
3150 Pleasant View Road
Middleton
Wisconsin
53562
USA

Date	Reference Number	Action
06 February 2015	8270322	Removal of the following significant subcontractors Transpack Medical Ltd for Packaging, Synergy Health Sterilisation UK Ltd for Gamma Irradiation, Medline Industries Inc for ETO Sterilization and SGM d.o.o for Manufacture, Natus Neurology Incorporated for Control of Sterilization, Design, Manufacture and Regulatory Compliance . Addition of significant subcontractor Paul E. Danchell A/S for Manufacture
08 November 2016	8603325	Change of EU Representative from Natus Europe GmbH, Robert-Koch-Str 1, 82152 Planegg, Germany to Natus Manufacturing Limited, IDA Business Park, Gort, Co. Galway, Ireland. Removal of the following significant subcontractors Medisize Ireland Ldt for Packaging and Synergy Health Westport Ltd for Gamma Sterilization.
Current	8907455	Certificate renewal. Rewording of scope to remove "Non-Imaging Ultrasound Devices for Diagnosis and Monitoring of Vascular Flow." Change in address of subcontractor Ad-Tech. Removal of subcontractor Medizintechnik Basler AG.

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EC Certificate - Full Quality Assurance System

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

No. **CE 618069**

Issued To: **Natus Manufacturing Limited**
IDA Business Park
Gort
Co. Galway
Ireland

In respect of:

Design and Manufacture of EMG Devices and Sterile and Non-sterile EMG/EEG Electrodes. Those aspects of Annex II relating to securing and maintaining sterility in the design and manufacture of Microelectrode Cables.

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: **2014-11-13** Date: **2019-11-19** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 618069

Issued To:

Natus Manufacturing Limited
IDA Business Park
Gort
Co. Galway
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102 MD 0106	Teca MyoJect Luer Lock Needle Electrodes Bo-ject Disposable Hypodermic Needle Electrodes	---
MD 0106	Teca Elite Disposable Concentric Needle Electrodes Teca Elite Disposable Monopolar Needle Electrodes Teca Disposable Monopolar Needle Electrodes Dantec DCN Disposable Concentric Needle Electrodes Value Line DCN Disposable Concentric Needle Electrodes	---
MD 1103	Clavis	---
MD 1103 MD 1301	Keypoint Focus Keypoint G4 Leadpoint Focus	---
Class Is		
MD 1301	Neuro MER Cables	---

First Issued: **2014-11-13** Date: **2019-11-19** Expiry Date: **2024-05-26**

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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 618069**
Date:	**2019-11-19**
Issued To:	**Natus Manufacturing Limited** **IDA Business Park** **Gort** **Co. Galway** **Ireland**

Subcontractor:	**Service(s) supplied**
Golden Bridge Electech Inc. Hsin Feng Lu Don, Hsin Cheng Dist., Shijie town, Dong Guan City, Guang Dong, China	**Manufacture**
Medisize Ireland Ltd High Road, Letterkenny, Co. Donegal, Ireland	**Packaging**
Paul E. Danchell A/S Lyngvej 8 Jyderup 4450 Denmark	**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

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

Certificate No:	**CE 618069**
Date:	**2019-11-19**
Issued To:	**Natus Manufacturing Limited** **IDA Business Park** **Gort** **Co. Galway** **Ireland**

Subcontractor:	**Service(s) supplied**
SteriPack Medical Poland Sp. z o.o. also registered under S.M.P. Sp. z o.o. Łęg, ul, Japońska 1 55-220 Jelcz-Laskowice Poland	**Packaging**
Synergy Health Westport Ltd (Synergy Health - AST - Westport) Lodge Road Westport County Mayo Ireland	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 618069**
Date: **2019-11-19**
Issued To: **Natus Manufacturing Limited**
IDA Business Park
Gort
Co. Galway
Ireland

Date	Reference Number	Action
13 November 2014	8195302	Initial Issue.
26 February 2014	8285252	Change of address to include "Co. Galway".
21 June 2018	8894466	Rewording of scope due to addition of new device to: " Design and Manufacture of EMG Devices and Sterile and Non-sterile EMG/EGG Electrodes. Those aspects of Annex II relating to securing and maintaining sterility in the design and manufacture of Microelectrode Cables." Addition of new subcontractors: - Paul E Danchell A/S - Golden Bridge Electech Inc. - SteriPack Medical - Sp Medical - Medisize
17 December 2018	8862798	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 618069**
Date: **2019-11-19**
Issued To: **Natus Manufacturing Limited**
IDA Business Park
Gort
Co. Galway
Ireland

Date	Reference Number	Action
Current	9774582	Certificate Renewal. Removal of subcontractor 'SP Medical Sp.z.o.o'. Amendment to name of subcontractor Medisize to Medisize Ireland Ltd. Amendment to name and address of SteriPack Medical Poland Sp. z.o.o. Japonska 1, Leg, ul, Jelcz-Laskowice 55-220, Poland to SteriPack Medical Poland Sp. z o.o. also registered under S.M.P. Sp. z o.o., Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice, Poland and Synergy Health Westport Ltd, Lodge Road, Westport, County Mayo, Ireland to Synergy Health Westport Ltd (Synergy Health – AST – Westport), Lodge Road, Westport, County Mayo, Ireland. Addition of Device Table.