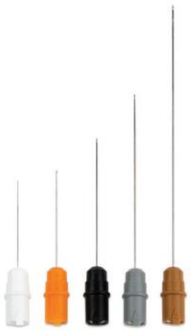
ELETTRODI AD AGO PER EMG

Elettrodi ad Ago Concentrici

Elettrodi ad Ago Concentrici per EMG Value

Venduti in confezione da 25 pezzi

- Affilati, il disegno della punta con triplo angolo incrementa il comfort
- del paziente riducendo la forza di inserzione
- Cannula in Acciaio Inossidabile fornisce resistenza e flessibilità per
- un efficiente inserzione e precise regolazioni
- Centraggio preciso, dell'elettrodo registrante in Acciaio Inossidabile
- per fornire registrazioni ripetibili ed accurate
- Rigorosi controlli di qualità assicurano affidabilità clinica
- Bassa Impedenza per un'accurata registrazione
- Pre-sterilizzati



Codice	*Lunghezza*	*Diametro ago (mm)*	*Area di registrazione (mm^2)*	*Colore*	*Confezione*
25V30	25mm	0,30 (30G)	0,03	Bianco	25 aghi
25V26	25mm	0,46 (26G)	0,07	Arancione	
37V26	37mm	0,46 (26G)	0,07	Nero	
50V26	50mm	0,46 (26G)	0,07	Grigio	
75V23	75mm	0,64 (23G)	0,07	Marrone	

Porta Ago per Elettrodi ad Ago Concentrici per EMG Value

Venduto singolarmente

- Cavo compatibile con la maggior parte degli strumenti EMG.
- Terminale Ago: Pogo Pin
- Connettore: 5-Pin DIN

Codice	*Descrizione*	*Confezione*
15VCBL	Porta ago (lunghezza cavo: 1,5m)	1 porta ago

EEG Electrodes

Other Reusable & Disposable Cup Electrodes

Grass® Reusable EEG Stamped-Cup Electrodes

- Choice of gold, silver or Ag/AgCl 10mm cups
- Pediatric 6mm Ag/AgCl cup available
- No-lift contour adjustable cup neck for low profile
- Molded plastic 1.5mm touchproof connector
- Six lead wire colors: two each:

Part Number	Cup Type	Lead Length	Quantity
019-477500	10mm Gold	39" (1.0m)	12/pkg
019-477600	10mm Gold	59" (1.5m)	12/pkg
019-478600	10mm Gold	79" (2.0m)	12/pkg
019-477700	10mm Gold	98" (2.5m)	12/pkg
019-477800	10mm Silver	39" (1.0m)	12/pkg
019-477900	10mm Silver	59" (1.5m)	12/pkg
019-478700	10mm Silver	79" (2.0m)	12/pkg
019-478800	10mm Silver	98" (2.5m)	12/pkg
019-478400	10mm Ag/AgCl	39" (1.0m)	12/pkg
019-478500	10mm Ag/AgCl	59" (1.5m)	12/pkg
019-478900	10mm Ag/AgCl	79" (2.0m)	12/pkg
019-479000	10mm Ag/AgCl	98" (2.5m)	12/pkg
019-479100	6mm Ag/AgCl Pediatric	59" (1.5m)	12/pkg

Reusable "Tangle Free" 10mm EEG Cup Electrodes

- Choice of gold, silver or Ag/AgCl cups
- Molded plastic electrode hub for sure grip and easy electrode placement
- Molded plastic 1.5mm touchproof connector
- Six lead wire colors: two each:

Part Number	Type	Lead Length	Quantity
019-414400	Gold	39" (1.0m)	12/pkg
019-413900	Gold	59" (1.5m)	12/pkg
019-433800	Gold	98" (2.5m)	12/pkg
019-414600	Silver	39" (1.0m)	12/pkg
019-414100	Silver	59" (1.5m)	12/pkg
019-417600	Ag/AgCl	39" (1.0m)	12/pkg
019-417700	Ag/AgCl	59" (1.5m)	12/pkg

Natus® Reusable "Tangle Free" 6mm Pediatric EEG Cup Electrodes

- Choice of gold or silver cups
- Molded plastic electrode hub for sure grip and easy electrode placement
- Molded plastic 1.5mm touchproof connector
- Six lead wire colors: two each:

Part Number	Type	Lead Length	Quantity
019-772500	Gold	39" (1.0m)	12/pkg
019-772600	Gold	59" (1.5m)	12/pkg
019-772100	Silver	39"(1.0m)	12/pkg
019-772200	Silver	59"(1.5m)	12/pkg

Natus Manufacturing Limited
IDA Business Park
Gort, County Galway
Ireland

European Declaration of Conformity to the Medical Device Regulation, (EU) 2017/745 of the European Parliament, and of the Council of 5 April 2017 on Medical Devices

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CE

Declaration Number: DOC-051800 Rev. B
Registered Product/Trade Name: Holder for Value Line DCN Disposable Concentric Needle Electrode
Single Registration Number: IE-MF-000000799
Product Catalog Number with associated UDI-DI: See Table 1, below
EMDN Code: N010101 ELECTROMYOGRAPHIC ELECTRODES

Intended Purpose:
Value Line DCN Holder is intended for use with Value Line DCN Needle Electrodes listed below (available in boxes of 25):

Order Number	Needle Length	Needle Diameter	Recording Area
25V30	25mm	0.30mm	0.02mm^2
25V26	25mm	0.46mm	0.07mm^2
37V26	37mm	0.46mm	0.07mm^2
50V26	50mm	0.46mm	0.07mm^2
75V23	75mm	0.64mm	0.07mm^2

Figure 1: Holder for Value Line DCN Disposable Concentric Needle Electrode

Natus Medical, Incorporated hereby declares that the above medical device(s), which bear the CE Mark, are in conformity with the applicable requirements of the Medical Device Regulation, (EU 2017/745 of the European Parliament, and of the Council of 5 April 2017 on Medical Devices).

Risk Classification/Rule: Class I / Annex VIII Rule I MDR 2017/745
Conformity Assessment Route: Annex II & III
Common Specifications Referenced: N/A

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

ISO Certificate No.: FM 603283 ISO 13485:2016

Issued by: BSI

Expiry Date: 04th November 2024

Additionally: Natus hereby declares conformity 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 Commission Delegated Directive 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances. It has been demonstrated that the requirements specified in Annex II of Directive 2015/863 have been met

Authorized Representative:	**Notified Body:**
N/A	N/A Class I device

Table 1: Holder for Value Line DCN**,** Catalog Numbers

Category	**Product Configuration/Model**	**Part (Catalog) Number**	**Basic UDI/DI**	**First lot produced**
Reusable Lead Cable	Holder for Value Line DCN	15VCBL	038283NA00011DQ	210308-D03SM

Name: *Seamus O'Connor*

Job Title: *Senior Director, Regulatory Affairs*

Place: *Gort, Galway, Ireland*

Date of Issue: 13 Dec 2021

Signature: 

By Royal Charter

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
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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.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Natus Medical Incorporated
5900 First Avenue South
Seattle
Washington
98108
USA

Holds Certificate No: **FM 702798**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture, distribution, installation and service of Medical Devices, including: Phototherapy lights (fluorescent, fiberoptic, LED), support - patient position, holder infant position, infant scales, pasteurizers washers, cerebral function monitor (electroencephalograph), pad neonatal eye, spectroradiometers, temperature probes, hearing protectors, protective restraint cooling caps for infants, products for the quantitative assessment and rehabilitation of balance disorders, and electroencephalograph systems, evoked response systems, otoacoustic emissions systems, hearing screeners and audiometers. Distributor of oral care kits, blood lancets and electrodes (ECG and CFM/EEG).

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2008-11-11
Effective Date: 2019-01-18
Latest Revision Date: 2019-02-28
Expiry Date: 2022-01-17

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