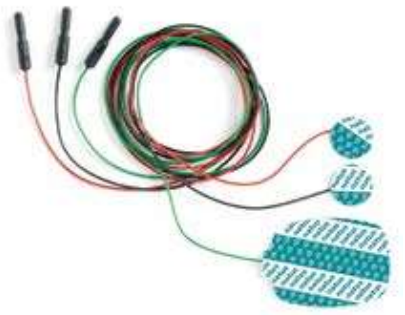
Adhesive Electrodes

Adhesive Electrodes with Lead Wires Attached

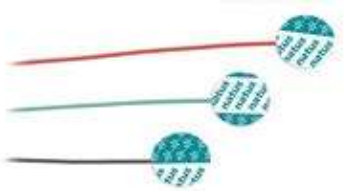
Disposable NCV Electrode Set with Leads



- Color-coded (red, green, black) attached lead wires terminate in 1.5mm touchproof connectors
- Two pre-gelled 20mm Ag/AgCl disc electrodes and one ground plate electrode per pouch
- Ideal for nerve conduction studies

Part Number	Type	Lead Length	Quantity	Compatibility
019-415200	NCV Electrode Set	39" (1m)	24 kits/pkg	Most systems that accept 1.5mm touchproof connectors

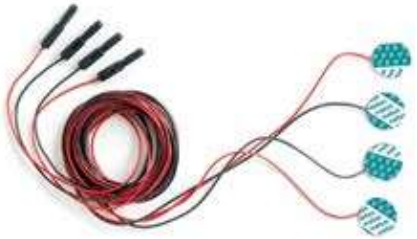
Disposable 3-Disc Electrode Set with Leads



- Color-coded (red, green, black) attached lead wires terminate in 1.5mm touchproof connectors
- Three pre-gelled 20mm Ag/AgCl disc electrodes per set
- Ideal for AEP and nerve conduction studies

Part Number	Type	Lead Length	Quantity	Compatibility
019-439400	Disc	20" (0.5m)	24 sets/pkg	Most systems that accept 1.5mm touchproof connectors
019-414200	Disc	39" (1m)	24 sets/pkg	

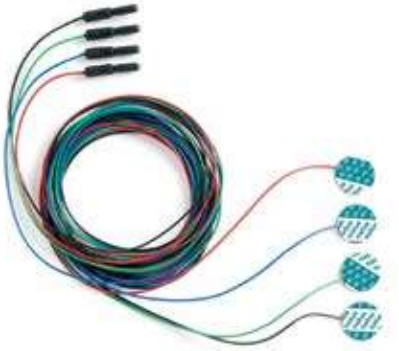
Disposable 2x2 Set with Leads



- Color-coded (two red, two black) attached lead wires terminate in 1.5mm touchproof connectors
- Four pre-gelled 20mm Ag/AgCl disc electrodes per pouch
- Ideal for IOM applications

Part Number	Type	Lead Length	Quantity	Compatibility
019-415000	Disc	59" (1.5m)	24 sets/pkg	Most systems that accept 1.5mm touchproof connectors
019-420800	Disc	118" (3m)	24 sets/pkg	

Disposable 4-Disc Electrode Set with Leads



- Color-coded (red, blue, green, black) attached lead wires terminate in 1.5mm touchproof connectors
- Four pre-gelled 20mm Ag/AgCl disc electrodes per pouch
- Ideal for PSG, NCS, SEP, AEP, EMG, ENG and IOM studies

Part Number	Type	Lead Length	Quantity	Compatibility
019-400400	Disc	39" (1m)	15 sets/pkg	Most systems that accept 1.5mm touchproof connectors
019-409000	Disc	79" (2m)	15 sets/pkg	

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

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 2797

Declaration Number:	DOC-063940, Rev 01
Registered Product/Trade Name:	Natus Brain Monitor and Embla Dx
Single Registration Number:	CA-MF-000004001
GMDN	11467
EMDN	Z121003
Product Catalog Number with associated UDI-DI:	See Table 1, below.
Intended Purpose:	

The Natus Brain Monitor Amplifier is intended to be used as an electroencephalograph: to acquire, display, store and archive electrophysiological signals.
The amplifier should be used in conjunction with Natus NeuroWorks™/ SleepWorks™ software to acquire scalp and intracranial electroencephalographic (EEG) signals as well as polysomnographic (PSG) signals.
The Natus Brain Monitor & Embla Dx Series Amplifier is intended to be used by trained medical professionals and is designed for use in clinical environments such as hospital rooms, epilepsy monitoring units, intensive care units, and operating rooms. It can be used with patients of all ages but is not designed for fetal use.
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:	IIa, Annex VIII, Rule 10
Conformity Assessment Route:	Annex IX Chapter I and III
Common Specifications Referenced:	N/A

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

Certificate No.: MDR 755097 R000

Issued by: BSI

Expiry Date: 1 February 2028

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:**
Natus Manufacturing Limited IDA Business Park Gort Co. Galway Ireland	BSI Group the Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands

Table 1: Natus Brain Monitor and Embla Dx Catalog Numbers

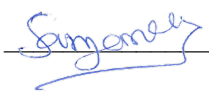
Category	Product Configuration/Model	Part (Catalog) Number	Basic UDI/DI
Natus Brain Monitor and Embla Dx	Natus Brain Monitor Kit	PK1274	038283NA00153ED
	Natus Brain Monitor Breakout Box	021911	038283NA00153ED
	Natus Embla NDx Amplifier	PK1270	038283NA00153ED
	Natus Embla NDx Breakout	021919	038283NA00153ED
	Natus Embla SDx Amplifier	PK1245	038283NA00153ED
	Natus Embla SDx Breakout	021920	038283NA00153ED
	Natus Base Unit	016862	038283NA00153ED
	Body positioning pod	022343	038283NA00153ED

Name: *Sanjay Mehta*

Job Title: *Director, Global Regulatory Affairs*

Place: *Oakville, Ontario, Canada*

Date of Issue: 02-Oct-2023

Signature: 

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate Number: FM 76793

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 (fiberoptic, LED), support - patient position, holder infant position, infant scales, pasteurizers washers, cerebral function monitor (electroencephalograph), pad neonatal eye, spectroradiometers, temperature probes, hearing protectors, product for the quantitative assessment and rehabilitation of balance disorders, and electroencephalograph systems, evoked response systems, optoacoustic emissions systems, hearing screeners and audiometers. Distributor of oral care kits, blood lancets and electrodes (ECG and CFM/EEG).

The design, manufacture, installation, service and distribution of systems and accessories for the diagnosis and monitoring of electrophysiological signals, photic, cortical stimulators and Ophthalmic Imaging Systems.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2003-10-29
Effective Date: 2021-08-06
Latest Revision Date: 2022-09-15
Expiry Date: 2024-08-05

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 755097 R000

Manufacturer: Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)

Address:
2568 Bristol Circle
Oakville
Ontario
L6H 5S1
Canada

Single Registration Number: CA-MF-000004001

EU Authorised Representative: Natus Manufacturing Limited

Address:
IDA Business Park
Gort
Co. Galway
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-02-02**

Current Issue Date: **2023-09-13**

Starting Validity Date: **2023-09-13**

Expiry Date: **2028-02-01**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 755097 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Electroencephalography Instruments - Software	Class IIa
Electroencephalograph Monitoring Devices.	Class IIa

First Issue Date: **2023-02-02**

Current Issue Date: **2023-09-13**

Starting Validity Date: **2023-09-13**

Expiry Date: **2028-02-01**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 755097 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-02-02	3496484	Issued
Current	30001553	Supplemented - Addition of device category 'Electroencephalograph Monitoring Devices'.

First Issue Date: **2023-02-02**

Current Issue Date: **2023-09-13**

Starting Validity Date: **2023-09-13**

Expiry Date: **2028-02-01**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.