EC CERTIFICATE

Number: 2021603CE02

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V
(Devices in Class IIa, IIb or III)

Manufacturer:

Cadwell Industries, Inc.

909 N. Kellogg Street
Kennewick, WA 99336
USA

For the product category(ies)

Electromyographs, Evoked Potential, and Electroencephalographs (EMG/EP/EEG) Devices for Use in Neurodiagnostics, Intraoperative Monitoring, and Electroencephalography

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 2021603CN, initially dated September 15, 2002
Addendum, initially dated March 15, 2005

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for the manufacture and final inspection for the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory.

The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until:	October 1, 2022
Issued for the first time:	March 15, 2005
Revised:	May 16, 2016
Reissued:	September 26, 2017

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: **2021603CE02**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Electromyographs, Evoked Potential, and Electroencephalographs (EMG/EP/EEG) Devices for Use in Neurodiagnostics, Intraoperative Monitoring, and Electroencephalography

Issued to:

Cadwell Industries, Inc.
909 N. Kellogg Street
Kennewick, WA 99336
USA

This certificate covers the following product(s):

Electromyography and Evoked Potential (EMG/EP) Devices (Class IIa)
- Sierra Summit
- Sierra Ascent

Electroencephalograph (EEG) device (Class IIa)
- Arc Essentia
- Arc Apollo

Disposable Nerve Stimulator Probes (Class IIa)
Electrode Plunger Clip-on Lead Wire (Class I sterile)
Electrode Multi Stage Clip-on Lead Wire (Class I sterile)

Initial date: March 15, 2005
Revision date: November 09, 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396