

# 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:

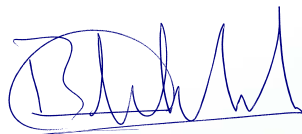
**Certification Notice 2021603CN, initially dated September 15, 2002  
Addendum, initially dated March 15, 2005**

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.



Managing Director



J.A. van Vugt  
Certification Manager

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

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# ADDENDUM

Belonging to certificate: 2021603CE02

1/1

## 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

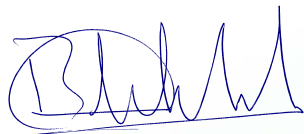
Electroencephalograph (EEG) device (Class IIa)

- Arc Essentia
- Arc Apollo
- Arc Zenith

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: April 30, 2019

DEKRA Certification B.V.

A blue ink signature of the Managing Director, consisting of stylized initials and a surname.

Managing Director

A blue ink signature of the Certification Manager, consisting of stylized initials and a surname.

J.A. van Vugt  
Certification Manager

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