

CERTIFICATE

Number: 3822018

The management system of:

Cadwell Industries Inc.

909 N. Kellogg Street
Kennewick, WA 99336
United States Of America

Manufacturer DUNS 09-855-4157

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

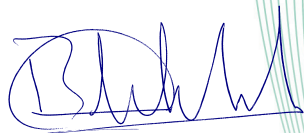
Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

Design and development, manufacture, service, and support of electroencephalograph, electromyograph and evoked potential instruments, electrodes, & sensors for use in Neurodiagnostics, Intraoperative monitoring of neural structures, & Sleep studies.

Certificate expiry date: 18 December 2021
Certificate effective date: 18 December 2018
Certified since: 18 December 2018

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-product-safety.com/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



