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

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

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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