

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Axelgaard Manufacturing Co., Ltd.

(FIN F001543)

Main Site: 520 Industrial Way, Fallbrook, CA 92028 USA

Additional Site1: 405 Industrial Way, Fallbrook, CA 92028 USA

Additional Site2: 999 E. Mission Road, Fallbrook, CA 92028 USA

(FIN F001983)

Additional Site3: 329 W. Aviation Road, Fallbrook, CA 92028 USA

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

The design and development, manufacture and distribution of hydrogel and non-invasive electrodes.

520 Industrial Way - corporate headquarters, purchasing, compliance & regulatory, IT, conversion, assembly, packaging, shipping, QC inspection

405 Industrial Way - engineering, design and creation of machine for production use

999 East Mission Road - receiving, gel production, quality lab/gel testing, incoming inspection

329 W Aviation Way - Design, gel production

Certificate Number:

0082299-01

Initial Certification Date:

2018-10-05

Date of Certification Decision:

2021-10-01

Certification Effective Date:

2021-10-04

Certification Expiry Date:

2022-10-04



intertek

A handwritten signature in black ink that reads "Calin Moldovean".

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.

900 Chelmsford Street

Lowell, MA, USA 01851



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request. Validity of this certificate may be verified at <http://www.intertek.com/business-assurance/certificate-validation/>

