

# 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, appearing to read "Calin Moldoveanu", written over a horizontal line.

**Calin Moldoveanu**

President, Business Assurance

Intertek Testing Services NA, Inc.  
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Lowell, MA, USA 01851

