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 Road - Design, gel production

Certificate Number:
0082299-02

Initial Certification Date:
2018-10-05

Date of Certification Decision:
2022-10-10

Certification Effective Date:
2022-10-10

Certification Expiry Date:
2024-10-04

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851