

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Axelgaard Manufacturing Co., Ltd.

(DUNS # 15-095-9401)

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

(DUNS # 94-576-0262)

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 OR 21 CFR 820.180 and 198, 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

Initial Certification Date:

2018-10-05

Certification Effective Date:

2018-10-05

Certification Expiry Date:

2021-10-04



Calin Moldovean

President, Business Assurance

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