

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

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

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:

0082299-03

Initial Certification Date:

2018-10-05

Date of Certification Decision:

2024-06-04

Certification Effective Date:

2024-06-04

Certification Expiry Date:

2027-06-03



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