Supplier Quality Self-Survey L4-27-4670 REV. A

Dear Valued Customer:

Axelgaard Manufacturing Co., Ltd. has received an increased number of questionnaires and surveys to be competed regarding our company and Quality Management System. Due to the high volume of requests, we are unable to respond to each one individually.

As most of these surveys request similar information, we have composed a standardized Supplier Quality Self Survey. This will ensure consistent information is provided to all our customers in a timely manner.

If more information is needed than what is provided in our Supplier Quality Self Survey, please contact your Customer Service Representative at cs@axelgaard.com.

We are confident this process will improve the management of information for our customers. We would like to thank you for your continued business.

Supplier Contact Information			
Company Name:	Axelgaard Manufacturing Co., Ltd.	Telephone No:	(760) 451-8000
Address and City	520 Industrial Way, Fallbrook	Primary Contact:	Customer Service Department
		Contact e-mail:	cs@axelgaard.com
State/Country	California, USA	For payments:	Accounting Department
		Contact e-mail	accounting@axelgaard.com
Postal Code:	92028	Website:	www.axelgaard.com

Company Overview	
Year Founded: 1985	Nature of Business: manufacture of hydrogel and medical electrodes
Number of Employees: >100	No. of Sites: 4
Public/Private: Privately Held	
Supply to Other Medical Device / Pharma / Biotechnology Customers? Yes	

Section 1. Quality & Regulatory	
Quality Systems Certification:	ISO 13485: 2016 with MDSAP certificate #0082299. The Company's notified body is Intertek Testing Services NA, Inc. Certificate available at www.axelgaard.com/downloads

Does the business manufacture products that are considered a medical device? ✓ Yes ☐ No

Regulatory Licenses/Approvals (copies available upon request):

- FDA Establishment License #2025066
- California Medical Device Manufacturing License #51770
- EC Declaration of Conformity. Authorized Representative (EC Rep) maintained in Denmark.
- Health Canada Medical Device License #72547 and #91417
- Taiwan Medical Device Manufacturing License #01866
- Rest of the world: Axelgaard investigates and determines regulatory requirements on a case by case basis and partners with authorized distributors

		Yes	No
1	Is there a written quality policy approved by the company management?	✓	☐
2	Is there a document / change control system?	✓	☐
3	Does the company ensure that purchased product conforms to specifications?	✓	☐
4	Are written procedures followed and processes operated in a stable, controlled environment?	✓	☐
5	Is finished and in-process material identified by a unique identification code that allows traceability?	✓	☐
6	Are records of all inspections maintained?	✓	☐
7	Are there systems in place to identify, segregate, and disposition non-conforming material?	✓	☐
8	Is there a formal, documented calibration program?	✓	☐
9	Are statistical techniques utilized to analyse, monitor, and improve production or business processes?	✓	☐
10	Is there a system in place to monitor effectiveness of corrective actions?	✓	☐
11	Is there a system in place to respond to customer feedback and complaints?	✓	☐
12	Is there a vigilance system in place for adverse event reporting, risk management and post market surveillance?	✓	☐
13	Does Axelgaard maintain adequate product liability insurance?	✓	☐
14	Does Axelgaard agree to notify customer in writing prior to making any material changes that affect the form, fit or function of the product, or the ability of the product to meet purchase requirements that your company purchases?	✓	☐
15	Does Axelgaard maintain an emergency response/business continuity plan?	✓	☐

Section 2. Environmental Compliance

- **REACH 1907/2006** (Registration, Evaluation, Authorization and Restriction of Chemicals). Annex XVII of REACH contains the list of restrictions of certain dangerous substances, mixtures and articles. Based on due diligence and the information provided by our suppliers, Axelgaard Manufacturing Co., Ltd. does not have registration responsibilities under the REACH regulation for declaration on the Candidate List of Substances of Very High Concern (SVHC). https://echa.europa.eu/candidate-list-table

- **RoHS3 2015/863** (Restriction of the use of certain hazardous substances in electrical and electronic equipment). Max limit 0.1% or 1000 ppm (parts per million) by weight of homogenous material. Based on due diligence and the information provided by our suppliers, Axelgaard Manufacturing Co., Ltd.'s products comply with RoHS3 restrictions and exemptions.
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2015_137_R_0003

- **WEEE 2012/19/EU** (Waste Electrical and Electronic Equipment). Since Axelgaard Manufacturing Co., Ltd. does not manufacture, or export any electrical or electronic equipment within the meaning of the directive, it does not have legislative obligations to comply.
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012L0019

- **Conflict Minerals**. Under the Dodd-Frank Act, the U.S. Securities and Exchange Commission (SEC) has adopted rules requiring publicly traded companies to disclose information about the use of certain minerals that originated in the Democratic Republic of Congo (DRC) or an adjoining country in their products. Since Axelgaard Manufacturing Co., Ltd. is not a publicly traded company, it does not have affirmative reporting requirements to the SEC. As part of our supply chain compliance activities, based on due diligence and the information provided by our suppliers, Axelgaard Manufacturing Co., Ltd.'s products do not include any of the minerals or derivatives impacted by the Act.
  https://www.sec.gov/info/smallbus/secg/conflict-minerals-disclosure-small-entity-compliance-guide.htm

- **California Proposition 65**. Officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986, Proposition 65 protects the state's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects or other reproductive harm, and requires businesses to inform Californians about exposures to such chemicals. Axelgaard Manufacturing Co., Ltd.'s products do not include any of the chemicals listed on the current Proposition 65 list. https://oehha.ca.gov/proposition-65/proposition-65-list

- **Latex Free.** Natural rubber latex or synthetic derivatives of natural rubber latex were not used as materials in the manufacture of Axelgaard Manufacturing Co., Ltd.'s products.

Axelgaard Manufacturing Co., Ltd. Supplier Quality Policy

Axelgaard Manufacturing Co., Ltd. is a leading manufacturer of hydrogel and electrodes. As part of the medical device industry, products or services provided by Axelgaard shall be manufactured and supplied in compliance with all applicable laws, regulations, quality standards and good manufacturing practice requirements.

I certify the Axelgaard Manufacturing Co., Ltd. self-survey is complete, accurate and that we have reviewed the most current revision of the above listed regulations for compliance as of the date of my signature below.			
Completed By:			
Name	Katherine Klem	Position	Manager of Regulatory Affairs
Signature		Date	January 24, 2024