PRESS RELEASE

Fallbrook, CA (October 9, 2018)--Axelgaard Manufacturing Co., Ltd. (AMC) is proud to announce that it has successfully upgraded its ISO13485:2016 certification to include the Medical Device Single Audit Program (MDSAP) standard. The MDSAP certification confirms that AMC completed an extensive auditing process to prove its Quality Management System meets regulatory requirements for the United States, Canada, Brazil and Australia.

“The MDSAP empowered AMC to leverage its regulatory resources by completing a single audit to prove compliance with regulatory requirements for multiple medical device markets,” said Emily Adams, Esq., Director of Compliance and Regulatory Affairs. “AMC understands that a globally harmonized approach to medical device manufacturing provides tremendous benefits to our customers and the end user.”

Completion of the MDSAP demonstrates AMC’s strong commitment to product quality and regulatory compliance. Some of the many benefits include:

- Enhances confidence in AMC’s product quality and regulatory expertise
- Supports continued licensing in Canada, where completion of the MDSAP will be required beginning in 2019
- Reduces the overall number of audits or inspections completed by AMC each year, thus optimizing the time and resources expended on audit activities
- Some participating regulatory authorities will use MDSAP audit outcomes as an alternative to their own inspections to process applications for medical device marketing authorization
- Improves the predictability of future audit outcomes through use of a standardized audit model

With this achievement, AMC continues to be the international leader in the design, development, and production of electrodes and other wellness products.