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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Axiom Medical, Inc.

(F003534) Main Site: 19320 Van Ness Avenue, Torrance, California, 90501, United States

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)
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), 21 CFR 821

The management system is applicable to:

Design, manufacture, and distribution of surgical wound drains and drain sets, catheters, sumps and sump sets, ligating devices, instrument jaw covers, and suction devices.

Certificate Number:
0096800-01

Initial Certification Date:
29 November 2019

Date of Certification Decision:
11 March 2021

Issuing Date:
11 March 2021

Valid Until:
28 November 2022

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Intertek

Calin Moldovean
President, Business Assurance

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