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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Sequel Special Products d.b.a Nissha Medical Technologies

(F004934)

Main Site: 1 Hillside Drive,

Wolcott, Connecticut, 06716, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Brazil: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Contract design and manufacture services for surgical & electro-mechanical surgical catheter and handpiece, attachable light for electrosurgical pencil, and monitoring electrodes. Including assembly, packaging, and packaging of passive implants.

Certificate Number:
0104256-02

Initial Certification Date:
2020-08-11

Certification Effective Date:
2023-08-10

Certification Expiry Date:
2026-08-10

ISO 13485:2016 CERTIFICATION TM intertek

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

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