

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 & electromechanical 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



intertek

Calin Moldovean President, Business Assurance

Intertek Testing Services NA, Inc. 900 Chelmsford Street Lowell, MA, USA 01851





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request. Validity of this certificate may be verified at http://www.intertek.com/business-assurance/certificate-validation/

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