intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Sequel Special Products d.b.a Nissha Medical Technologies, Biomedical Innovations

(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: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

United States: 21 CFR 820.180 and 198, 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 electro-mechanical surgical catheter and handpiece, attachable light for electrosurgical pencil. Including assembly, packaging, and packaging of passive implants.

Certificate Number:
0104256

Initial Certification Date:
11 August 2020

Date of Certification Decision:
10 August 2020

Issuing Date:
11 August 2020

Valid Until:
10 August 2023

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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 organisation 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/