

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Nissha Medical Technologies (Ohio), Inc.

(FIN F005474)

Main Site: 93 N Pleasant Street,

Norwalk, Ohio, 44857, 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, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68

The management system is applicable to:

Contract manufacture of medical endoscopes, sheaths, obturators, adapters, seals, lithotripsy instruments, cleaning brushes, manual surgical instruments, electrosurgical instruments, working elements, cords and vacuum curettage systems and accessories for use in urology and gynecology. The contract manufacture of medical device components for use in ENT, urology, and gynecology, electrosurgical and minimally invasive surgical procedures. Servicing of reusable endoscopes and related instrumentation. Certificate Number: 0120933

Initial Certification Date: 2022-03-23

Date of Certification Decision: 2022-03-23

Certification Effective Date: 2022-03-23

Certification Expiry Date: 2025-03-22







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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