

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: 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)

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:

0120933-01

Initial Certification Date:

2022-03-23

Date of Certification Decision:

2024-06-11

Certification Effective Date:

2024-06-11

Certification Expiry Date:

2025-03-22



intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
4700 Broadmoor SE, Suite 200
Kentwood, MI, USA, 49512

