

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

**CEA Medical Manufacturing, Inc. d.b.a  
Nissha Medical Technologies**  
(F003482)

Main Site: 1735 Merchants Court  
Colorado Springs, Colorado 80916 United States

Additional site: 1755 Merchants Court, Colorado Springs, CO 80916 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), 21 CFR 821

**The management system is applicable to:**

*Contract design, manufacturer, assembly, and packaging of surgical and biopsy devices including: clamps, electrosurgical devices and accessories, laparoscope, ultrasonic surgical devices, and catheter cables.*

*Additional Site1: Manufacturing and distribution.*

**Certificate Number:**

0096294-03

**Initial Certification Date:**

2019-11-29

**Date of Certification Decision:**

2022-11-18

**Issuing Date:**

2022-11-28

**Valid Until:**

2025-11-28



**intertek**

**Calin Moldovean**

President, Business Assurance

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