

## **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: 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, manufacture, assembly and packaging of surgical and biopsy devices including; shunts, clamps, electrosurgical devices and accessories, laparoscope, ultrasonic surgical devices, and catheter cables.

Certificate Number: 0096294

**Revision Level: 05** 

**Initial Certification Date:** 2019-11-29

Last certificate expiry date: 2025-11-28

Date of last recertification audit: 2025-08-28

Certification cycle start date: 2025-12-01

**Issuing date: 2025-12-01** 

**Certification Expiry Date: 2028-11-28** 





intertek

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