

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:

0096294-02

Initial Certification Date:

2019-11-29

Date of Certification Decision:

2021-07-09

Issuing Date:

2021-07-09

Valid Until:

2022-11-28



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