

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

CEA Global Dominicana d.b.a Nissha Medical Technologies

Main Site: Solares 8 & 9 Manzana 5A, Zona Franca Industrial San Pedro de Macoris, Dominican Republic (F004237)

Additional Site: Solares 02 & 03 Manzana 2B, Zona Franca Industrial San Pedro de Macoris, Dominican Republic

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:

The contract manufacture, assembly and packaging of non-sterile medical products including guidewires, electrical cables, tubes for endoscopy, septal stapler, and components for medical monitoring devices.

Certificate Number:

0099084

Revision Level: 06

Initial Certification Date:

2020-02-21

Date of Certification Decision:

2026-01-29

Certification Effective Date:

2026-02-20

Certification Expiry Date:

2029-02-20



intertek

Mark Thomas

Executive Vice President

Assurance, Sustainability, AgriWorld & Food

Intertek Testing Services NA, Inc.

4700 Broadmoor SE, Suite 200

Kentwood, MI, USA, 49512

