

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, Dominica Republic (F004237)

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

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)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68

The management system is applicable to:

Contract Manufacturing, assembly and packaging of medical products including guidewires, electrical cables, tubes for endoscopy, Septal Stapler, and components for medical monitoring devices

Certificate Number:

0099084-04

Initial Certification Date:

2020-02-21

Date of Certification Decision:

2023-02-01

Certification Effective Date:

2023-02-20

Certification Expiry Date:

2026-02-20



intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.

900 Chelmsford Street

Lowell, MA, USA 01851

