

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, endotubes, Septal Stapler, and components for medical monitoring devices.

Certificate Number:

0099084-03

Initial Certification Date:

2020-02-21

Date of Certification Decision:

2021-07-09

Certification Effective Date:

2021-07-09

Certification Expiry Date:

2023-02-20



intertek

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