

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## CEA Global Dominicana d.b.a. Nissha Medical Technologies

(F004237)

Main Site: Solares 8 & 9 Manzana 5A, Zona Franca Industrial San Pedro de Macoris, Dominica Republic

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)

The management system is applicable to:

Manufacture of guidewires, cables and components for medical monitoring devices.

**Certificate Number:**

0099084-02

**Initial Certification Date:**

21 February 2020

**Date of Certification Decision:**

21 February 2020

**Issuing Date:**

19 November 2020

**Valid Until:**

20 February 2023



**Intertek**

**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA, Inc.

900 Chelmsford Street

Lowell, MA, USA 01851

