

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

Additional site: Solares 2 & 3 Manzana 2B, Zona Franca Industrial San Pedro de Macoris, Dominica Republic

has been registered by Intertek as conforming to the requirements of

EN ISO 13485:2016

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.

*Previously certified by Intertek Certification AB to date 2 September 2020

Certificate Number:

0105667-03

Initial Certification Date:

16 March 2011*

Date of Certification Decision:

13 February 2023

Certificate Valid Date:

21 February 2023

Certificate Expiry Date:

20 February 2026



Ackred. nr. 10426
Certifiering av ledningssystem
ISO/IEC 17021-1



Intertek

Mikael Hagelin

Certification Authority, Intertek Medical
Notified Body AB

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