

CERTIFICATE

Number: 3812267

The management system of the organization(s) and locations mentioned on the addendum belonging to:

OSCOR CARIBE LLC

Zona Franca Las Americas, Nave A1-2
Santo Domingo
Dominican Republic

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

Contract Manufacturing, packaging, and distribution, including Ethylene Oxide Sterilization of Permanent Implantable Pacemaker Leads, Lead Adaptors, Temporary Pacing Leads, Neurostimulation Leads, Introducer Sets, Catheters, Guidewires, Guiding Sheaths, Delivery Sheaths, Extension Cables and Port Plugs Adaptors for Interventional Cardiology, Cardiac Rhythm Management, and related implantable and vascular applications.

The provision of Ethylene Oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014 and ISO 11135:2014.

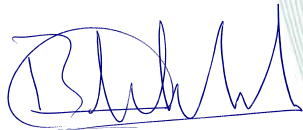
Certificate expiry date: **30 April 2029**

Certificate effective date: 30 April 2026

Certified since: 26 July 2014

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



F. Godeke
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: Number: 3812267

The management system of the organization(s) and/or location(s) of:

OSCOR CARIBE LLC

Zona Franca Las Americas, Nave A1-2
Santo Domingo
Dominican Republic

Certified organization(s) and/or locations:

Different scope

OSCOR CARIBE LLC
Zona Franca Las Americas, Nave GP-5
Santo Domingo
Dominican Republic

Ethylene Oxide Sterilization and Final Packaging of

- Permanent Implantable Pacemaker Leads
- Lead Adaptors
- Temporary Pacing Leads
- Neurostimulation Leads
- Introducer Sets
- Catheters
- Guidewires
- Guiding Sheaths
- Delivery Sheaths
- Extension Cables
- Port Plugs Adaptors

Addendum expiry date: **30 April 2029**

Addendum effective date: 30 April 2026