# CERTIFICATE

Number: 3823559

The management system of:

## Oscor Inc.

**4875 Palm Harbor Blvd.**
**Palm Harbor, FL 34683**
**United States Of America**

Manufacturer Facility Identifier F001479

Conforms with the following standard and regulatory requirements:

# ISO 13485:2016

| | |
|---|---|
| Australia: | Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure, Therapeutic Goods (Medical Devices) Regulations,2002 OR Schedule 3 Part 4 - Production Quality Assurance Procedure |
| Brazil: | RDC ANVISA n. 665/2022, 551/2021, and 67/2009 |
| Canada: | Medical Devices Regulations - Part 1- SOR 98/282 |
| Japan: | MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act |
| United States: | 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D, 21 CFR 820 and 21 CFR 821 |

Scope: Design, Development, Manufacture and Distribution of Permanent Implantable Pacemaker Leads and Adaptors, Heart Wires, Temporary Pacemaker Leads, Introducer Sets, Occlusion Balloon Catheters, Angiography Catheters, Delivery Sheaths, Guidewires, Vein Picks, Ligature Sleeves, Syringes, Valve Bypass Tools, Transvalvular Insertion Tools, and Thermoplastic Straighteners for using in Cardiac Applications, Renal Applications, Interventional Radiology and General Diagnostics. Manufacture of Neurostimulation Leads.

Certificate expiry date: 2026-01-31
Certificate effective date: 2024-06-27
Certified since: 2020-01-31

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Certification Manager



The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https:/www.dekra-checkme.com/org

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM