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
Brazil:	RDC ANVISA n. 665/2022, 551/2021, and 67/2009
Canada:	Medical Devices Regulations - Part 1- SOR 98/282 and Medical Devices Regulations - Part 1.1 - 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

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: 2029-01-31
Certificate effective date: 2026-01-31
Certified since: 2020-01-31

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

F. Godeke
Certification Manager

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