

CERTIFICATE

Number: 3321100

The management system of:

Oscor Inc.

4875 Palm Harbor Blvd.

Palm Harbor, FL 34683

United States Of America

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

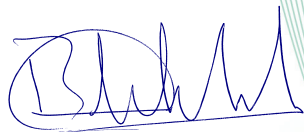
Scope:

Design, Development, Manufacture, including Ethylene Oxide Sterilization, 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.


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: 31 January 2029
Certificate effective date: 31 January 2026
Certified since: 26 February 2019

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



F. Godeke
Certification Manager

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