



Orion Registrar, Inc.

Thorough and Fair Auditing

Certificate of Certification

This is to certify the Quality Management System of:

Cardea Catheter Innovations, LLC

**90 Great Oaks Blvd., Suite 107
San Jose, CA 95119 USA**

Has been assessed by Orion Registrar and found to be in compliance with the following Quality Standard:

ISO 13485:2016

The Quality Management System is applicable to:

The design, manufacture, packaging, labeling, storage, and delivery of high-quality extrusions, balloons and catheters.

The Certification period is from

May 31, 2019 to May 30, 2022

This certification is subject to the company maintaining its system to the required standard, and applicable exceptions, which will be monitored by Orion.

Client ID: 9493

Certificate ID: 1016538



Paul M. Burck

June 3, 2019

Paul M. Burck, President

Date