Orion Registrar, Inc.
Thorough and Fair Auditing

Certificate of Certification

This is to certify the Quality Management System of:

NovelCath
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

March 14, 2022 to May 30, 2025

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: 1024539

ANAB
ANSI National Accreditation Board
A C C R E D I T E D
ISO/IEC 17021-1
MANAGEMENT SYSTEMS
CERTIFICATION BODY

IAF
MEMBER OF MULTILATERAL
RECOGNITION ARRANGEMENT

Paul M. Burck, President   April 11, 2022

                                                      Date