



Certification is conditional on maintaining the required performance standards throughout the certified period of registration
Orion Registrar, Inc., 7502 W. 80th Avenue, STE. 225 Arvada, Colorado 80003-2128, USA

The management system of Certificate Number **252681**

NovelCath

3301 Leonard Court, Santa Clara, CA 95054, USA

has been assessed and certified as meeting the requirements of

ISO 13485: 2016

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

Further clarifications regarding the scope of this certificate and the applicability of requirements may be obtained by consulting the certifier.

Valid from

Initial Certification: Friday, May 31, 2019

Current Cycle Start: Tuesday, May 31, 2022

Latest Issue: Tuesday, February 20, 2024

Expiry Date: Friday, May 30, 2025

subject to annual assessments

Certification Structure: Single Site

Authorised by

A handwritten signature in black ink, appearing to read "Mike Tims".

Mike Tims
Chief Executive Officer



www.orioncertification.com

Certificate issued by Orion Registrar, Inc.