



America

CERTIFICATE

No. QS2 050264 0008 Rev. 03

Certificate Holder:

Donatelle Plastics, LLC
501 County Road E-2 Extension
New Brighton MN 55112
USA

Certification Mark:



Scope of Certificate:

Contract Manufacturer of Sterilized Medical Devices and Medical Device Components for Cardiac, Diagnostic, Drug Delivery, Neuromodulation, Ophthalmics, Orthopedics, Surgical Technologies and Vascular Products Starting at Product Development and Prototyping through Shipment of Finished Product to Customers

Standard:

ISO 13485:2016

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

721004665

Effective Date:

2024-11-22

Expiry Date:

2026-08-31

Page 1 of 1

Date of Issue: 2024-11-27

(Renee Walker)
Director, US Certification Body, MHS