



America

# CERTIFICATE

No. QS2 050264 0008 Rev. 01

**Certificate Holder:** Donatelle Plastics, Inc.  
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.:** 72165614

**Effective Date:** 2021-04-19

**Expiry Date:** 2023-08-31

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**Date of Issue:** 2021-04-20

( Tina Israel )  
Manager, US Certification Body,  
Medical and Health Services