

This is to certify that

FMI LLC.

500 Bond Street, Lincolnshire, Illinois 60069, USA

operates a

Quality Management System

which complies with the requirements of

ISO 13485:2016

for the following scope of certification

Manufacture of customer-specified engineered molded rubber products as non-active implantable medical devices. Contract Medical Device Packaging.

Certificate No.: CERT-0125620

1686871 File No.:

October 6, 2021 Issue Date:

Original Certification Date: June 20, 2017 Certification Effective Date: October 17, 2021

October 16, 2024 Certificate Expiry Date:

Frank Camasta Global Head of Technical Services SAI Global Assurance







