



# CERTIFICATE OF REGISTRATION

This is to certify that  
**FMI LLC.**

2375 United Lane Elk Grove Village, Illinois 60007 USA

Refer to Attachment to Certificate of Registration dated October 18, 2018 for additional certified sites  
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.**

Certificate No.: CERT-0125618  
File No.: 1635727  
Issue Date: October 18, 2018

Original Certification Date: January 7, 2013  
Certification Effective Date: October 18, 2018  
Certification Expiry Date: October 17, 2021

Kevin Goodwin  
General Manager Technical Services  
SAI Global Assurance



# ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0125618 issued on October 18, 2018

File No.		Effective Date
010837	<b>FMI LLC.</b> 2382 United Lane Elk Grove Village , Illinois 60007-6815 USA Administration, purchasing, human resources, quality management and non-conforming material quarantine.	October 18, 2018
1635727	<b>FMI LLC.</b> 2375 United Lane Elk Grove Village , Illinois 60007 USA Manufacturing (including clean room), customer service/order management, incoming inspection, in-process inspection, preventive maintenance, calibration, non-conforming material control, packaging and shipping.	October 18, 2018
1635728	<b>FMI LLC.</b> 2285 Devon Ave Elk Grove Village , Illinois 60007 USA Product inspection (in-process and final)	October 18, 2018
1686871	<b>FMI LLC.</b> 500 Bond Street Lincolnshire , Illinois 60069 USA Production, Non-conforming Product, Training, Infrastructure and Calibration.	October 18, 2018

These registrations are dependent on FMI LLC. (File No. 1635727) maintaining their scope of registration to ISO 13485:2016