

This is to certify that

Thermo Fisher Scientific

Chromatography & Mass Spec Division 355 River Oaks Parkway San Jose, California 95134 USA

Refer to Attachment to Certificate of Registration dated September 25, 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

Design, manufacture, install, service and distribute In Vitro Diagnostic instruments and software.

Certificate No.: CERT-0125192 Original Certification Date: September 28, 2012

File No.: 1605800 Certification Effective Date: September 26, 2018 Issue Date: September 25, 2018 Certification Expiry Date: September 25, 2021

Kevin Goodwin General Manager Technical Services SAI Global Assurance







ATTACHMENT TO

CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0125192 issued on September 25, 2018

File No. Effective Date

1605800 Thermo Fisher Scientific September 26, 2018

Chromatography & Mass Spec Division

355 River Oaks Parkway San Jose , California 95134 USA

Design, manufacturing, distribution purchasing, inspection processes, human resources,

environment and infrastructure.

1614441 Thermo Fisher Scientific September 26, 2018

Chromatography & Mass Spec Division
101 Constitution Boulevard Franklin , Massachusetts 02038 USA

Design, manufacture, install, service and distribute In Vitro Diagnostic instruments and software.