Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Thermo Fisher Scientific Oy
Ratastie 2
FI-01620 Vantaa
Finland

DUNS Number: 54-009-6708

Holds certificate No: **MDSAP 691174**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1- SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

The design and development, manufacturing, service, installation and distribution of in vitro diagnostics medical devices including clinical chemistry analysing systems, clinical liquid chromatography and mass spectrometry systems, laboratory automation and in vitro diagnostic assays and reagents.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-03-25 Effective Date: 2019-03-25 Expiry date: 2021-03-31

BSI Group America Inc. is an MDSAP authorized auditing organization

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