Certificate of Approval

This is to certify that the Management System of:

Trek Diagnostic Systems Ltd, a part of Thermo Fisher Scientific

Units 17-19, Birches Industrial Estate, East Grinstead, RH19 1XZ, United Kingdom
MDSAP Facility Identifier: F003639

has been audited by Lloyd's Register Quality Assurance and found to conform to the following audit criteria:

ISO 13485:2016

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(Excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

RDC ANVISA n. 16/2013
RDC ANVISA n. 23/2012
RDC ANVISA n. 67/2009

Canada:

Medical Devices Regulations – Part 1- SOR 98/282

Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68
PMD Act

United States:

21 CFR 803
21 CFR 806
21 CFR 807 – Subparts A to D
21 CFR 820

Cliff Muckleroy - Area Operations Manager Americas
Issued by: Lloyd's Register Quality Assurance, Inc.

Certificate approval number: LRQ0962758
Effective date: 2019 November 7
Expiry date: 2022 November 6
Certificate issue number: 10236007

Original approval:
MDSAP/ISO 13485 – 2019 November 7

The scope of approval is shown on the next page and bears the same certificate identity number

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

Certificate of Approval

Approval number: MDSAP – 00022693

Certificate issue number: 10236007

The scope of this approval is applicable to:

Design and development, manufacture and distribution of In Vitro diagnostic kits for identification and susceptibility of microorganisms. Design, control of manufacture, installation and servicing of associated equipment.

Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

Issued byLloyd's Register Quality Assurance, Inc., 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, United States