

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

Original approval:

Effective date: 2019 November 7

MDSAP/ISO 13485 – 2019 November 7

Expiry date: 2022 November 6

Certificate issue number: 10236007

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



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

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.



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