

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Trek Diagnostic Systems Ltd.
Units 17-19, Birches Industrial Estate
East Grinstead
West Sussex
RH19 1XZ
United Kingdom

Facility ID Number: F006251

Holds Certificate No:

MDSAP 773975

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

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

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-08-04

Effective Date: 2022-11-07

Expiry Date: 2025-11-06



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