

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ARK Diagnostics, Inc.
48089 Fremont Blvd
Fremont
California
94538
USA

Holds Certificate Number:

FM 704400

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture and distribution of in vitro diagnostic (IVD) immunoassays for therapeutic drug monitoring, urine drug testing and other molecules.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2007-10-25

Latest Revision Date: 2022-09-15

Effective Date: 2022-02-12

Expiry Date: 2025-02-11

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