

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

New Day Diagnostics, LLC

6701 Baum Drive
Suite 110
Knoxville
Tennessee
37919
USA

Holds Certificate Number:

MD 807136

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

Design, Development, Manufacturing, and Distribution of in vitro diagnostic test kits for use in the detection of cancer tumor biomarkers and infectious disease agents. The provision of services for the analytical validation and clinical validation of in vitro diagnostic test kits.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-08-19

Latest Revision Date: 2024-08-19

Effective Date: 2024-10-23

Expiry Date: 2027-10-22

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