

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Tetracore, Inc.
77 Upper Rock Circle
Rockville
Maryland
20850
USA

Holds Certificate Number: MD 787351

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

Design, development, manufacture, and distribution of in- vitro diagnostic reagents, test kits, instruments and accessories for the diagnosis and management of infectious diseases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2024-01-08

Latest Revision Date: 2024-01-08

Effective Date: 2024-01-08

Expiry Date: 2027-01-07

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