

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Diversatek Healthcare
9150 Commerce Center Circle #500
Highlands Ranch
Colorado
80129
USA

Holds Certificate Number: FM 712057

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

The design and development, manufacture, servicing and distribution of active and non-active gastrointestinal system diagnostic medical devices, including the following: Reflux Monitoring Systems, Gastrointestinal Manometry Systems, pH and Impedance Probes, Mucosal Integrity Testing Systems, and Related Accessories, Catheters, and associated Cables.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-05-03

Latest Revision Date: 2022-09-15

Effective Date: 2022-04-06

Expiry Date: 2025-04-05

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