



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: ELITechGroup Inc.

370 West 1700 South

Logan Utah 84321 USA

Holds Certificate No: FM 703046

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

The design, manufacture, distribution and servicing of automated slide stainers, cytocentrifuges, cystic fibrosis sweat testing systems, and osmometers, and proprietary standards, controls disposables and reagents for use with these types of equipment. Manufacture and distribution of controls, standards, consumables, accessories and supplies for in vitro diagnostic systems, laboratory equipment, and erythrocyte sedimentation rate test systems.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-05-12 Effective Date: 2022-01-11 Latest Revision Date: 2021-12-23 Expiry Date: 2025-01-10

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...making excellence a habit."



