

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Norgen Biotek Corp.
3430 Schmon Parkway
Thorold
Ontario
L2V 4Y6
Canada

Holds Certificate No:

FM 547994

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

Design, development, manufacturing and marketing of sample preparation kits for the collection, preservation, isolation, concentration and clean-up of DNA, RNA, and Protein from a variety of biological samples including saliva, urine, blood, plasma/serum, cells, bacteria, viruses, and tissues including FFPE for use in research applications and for IVD use.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-08-07

Latest Revision Date: 2021-09-10

Effective Date: 2021-06-18

Expiry Date: 2024-06-17

