

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

BIO NUCLEAR DIAGNOSTICS INC

Main Site: 1791 Albion Road, Toronto, Ontario, M9W 5S7, Canada
(DUNS #24-336-2902)

Additional site: 2100 Codlin Crescent, Toronto, Ontario, M9W 7J2,
Canada
(DUNS# 24-336-2902)

has been registered by Intertek, an MDSAP recognised auditing organisation,
as conforming to the requirements of:

ISO 13485:2016

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Main site: Manufacture of Medical Examination Gloves, Cytology Products, Vaginal Speculum, and Diagnostic Kits for the testing of Drugs of Abuse, Hormones and Pregnancy.

Manufacture of Microscopy Products, Pipettes, Sharps Containers, Tourniquets, Wound Care Products, First Aid Kits.

Distribution, installation and service of nucleic acid detection and monitoring system; and distribution of diagnostic kits, needles and syringes, and general hospital and medical supplies.

Additional site: Warehousing.

Certificate Number:

0063241-01

Initial Certification Date:

2017-05-31

Certificate Effective Date:

2018-05-01

Certificate Expiry Date:

2020-05-30



Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

