

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Diagnostics Biochem Canada Inc.

(DUNS # 20-771-8438)

Main Site: 384 Neptune Crescent  
London, Ontario N6M 1A1 Canada

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

### ISO 13485:2016

**Brazil:** Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

**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)

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

### The management system is applicable to:

*The design, development and manufacturing of in-vitro diagnostic test kits and reagents used in the diagnosis of endocrine disorders, disease status, cardiac markers, autoimmune status, fertility testing and cancer.*

**Certificate Number:**

0084108

**Initial Certification Date:**

2018-11-19

**Certification Effective Date:**

2018-11-19

**Certification Expiry Date:**

2021-11-18



**Calin Moldovean**

President, Business Assurance

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