

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Medica Corporation

(FIN F002402)

Main Site: 5 Oak Park Drive, Bedford, Massachusetts, 01730, United States

Additional Site: 3 Oak Park Drive, Bedford, Massachusetts, 01730, United States

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:

*Design, Development, Manufacture, Service, Installation and Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.*

**Certificate Number:**

0089217-01

**Initial Certification Date:**

2019-04-19

**Date of Certification Decision:**

2022-03-24

**Certification Effective Date:**

2022-04-18

**Certification Expiry Date:**

2025-04-18



intertek

**Calin Moldovean**

President, Business Assurance

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

