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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

BioMedica Diagnostics Inc.

Main Site: 500 West Avenue, Stamford, Connecticut 06902
United States
(DUNS #08-060-0606)

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

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

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, manufacture and distribution of in-vitro diagnostic and prognostic tests and reagents for hemostasis, thrombosis, fibrinolysis, and cancer for hospitals, testing laboratories, and the pharmaceutical industry.

Certificate Number:
0077384-00

Initial Certification Date:
2018-06-27

Certification Effective Date:
2018-06-27

Certification Expiry Date:
2021-06-26

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

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