CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Biodex Medical Systems, Inc.

(FIN F000751)

Main Site: 49 Natcon Drive

Shirley, New York, 11967, United States

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, installation, service and support of physical medicine products, rehabilitation products, and radiology products and accessories. The service and support of nuclear medicine products and accessories.

Certificate Number:
0084059-02

Initial Certification Date:
2018-12-03

Date of Certification Decision:
2022-02-01

Certification Effective Date:
2022-02-01

Certification Expiry Date:
2024-12-02

Calin Moldovean
President, Business Assurance

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