

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Biodex Medical Systems, Inc.

(DUNS # 04-383-3813)

Main Site: 20 Ramsay Road
Shirley, New York, 11967, United States

Additional 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 and service of physical medicine, rehabilitation products, radiology equipment and accessories, radiation safety supplies and accessories, as well as nuclear medicine and accessories.

Additional Site: Fabrication & Assembly/Receiving/Warehousing/Shipping

Certificate Number:

0084059

Initial Certification Date:

2018-12-03

Certification Effective Date:

2018-12-03

Certification Expiry Date:

2021-12-02



Calin Moldovean

President, Business Assurance

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