

BIODEX

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Radionuclide Dose Calibrators	Atomlab 500	086-330/-331/-332/-336
	Atomlab 400	086-335
Accessories & Replacement Parts		008-015, 075-596, 086-241, 086-242, 086-243, 086-338, 086-423, 086-435, 086-509
Serial Number	N/A	

MANUFACTURER

Name of Company	Address	Representative
Biodex Medical Systems, Inc.	20 Ramsey Road Shirley, NY 11967-4704 USA	Clyde Schlein <i>Vice President, Regulatory Affairs & Compliance</i>

AUTHORIZED REPRESENTATIVE

Name of Company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	Phone: +31.70.345.8570 Fax: +31.70.346.8570

REGISTRATION INFORMATION

Notified Body and ID#	CE Certificate No & Expiration Date	Date CE Marking First Applied
Intertek Services	41312458-01 7-20-2023	N/A

CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Application
Class I Measuring Rule #12 Annex V	Annex V of MDD 93/42/EEC Council Directive	EN60601-1 Ed3 EN 60601-1-2:2007 IEC 60601-1-1:2000 Ed 2 IEC 601-1:1988 +A1 +A2 UL 60601-1:2003 CAN/CSA c22.2 No.:601-1-M90 IEC 60601-1-4:2000

QUALITY SYSTEM REGISTRAR

Intertek Services Certified Quality Management System:
ISO 13485:2016 Certificate: 0084059

Biodex Medical Systems, Inc. declares the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.

Company Representative: Clyde Schlein

Title: Vice President, Regulatory Affairs & Compliance

Date: May 1, 2019

No. 135 Rev. G

Biodex Medical Systems, Inc.

20 Ramsey Road, Shirley, New York, 11967-4704, Tel: 800-224-6339 (Int'l 631-924-9000), Fax: 631-924-9241, Email: info@biodex.com, www.biodex.com

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Signature: 

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