

# BIODEX

## DECLARATION OF CONFORMITY

### PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Lead-Lined Cabinet	Storage Safe, PET unit dose cabinet	042-407, 244-006, 244-200
	Radioisotope storage cabinet	244-205, 244-110, 244-111
	Decay Cabinet, Waste Cabinet	244-112, 244-140, 244-141
	Preparation Enclosure Base Cabinet	244-142, 244-190, 244-191
	Decay and Storage Cabinet	244-007, 244-008, 244-160
	Waste and Storage Cabinet	
	Sink and Waste Cabinet	244-161, 244-162, 244-150
	Unit Dose Cabinet, Generator and Storage Cabinet, PET unit dose table, Phantom Cabinet, Lead-Lined Refrigerator, Cyclotron workbench, Steel Table	244-151, 244-152, 244-170 244-171, 244-172, 244-130 244-131, 244-132, 244-181 244-182, 244-120, 244-121 244-122, 244-009, 244-004 244-005, 042-456

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 &amp; 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

### CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Application
Class I Rule 1	Annex VII of MDD 93/42/EEC Council Directive	N/A

### QUALITY SYSTEM REGISTRAR

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

Biodex Medical Systems, Inc. declares the abovementioned 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. 124 Rev. F

Signature:

