

# BIODEX

## DECLARATION OF CONFORMITY

### PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Lead Brick	Lead Bricks, Lead Brick Cave	002-246,002-248,001-100 001-200,001-300,001-400 001-500,001-600,001-132 001-130,001-135,001-148 001-147,001-142,001-149 001-145,001-140,042-434 042-425,042-417,042-426 042-435

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:

