

# BIODEX

## DECLARATION OF CONFORMITY

### PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Personnel Protective Shield, Mobile X-Ray Barrier	Clear Lead Mobile X-Ray Barrier	042-580, 042-582 042-583, 042-585

**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 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. 148 Rev. A

Signature:



Biodex Medical Systems, Inc.

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