

BIODEX

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

| Type of Equipment | Product Name(s) | Model/Number(s) |
|----------------------------|-------------------------|------------------|
| Personnel Radiation Shield | Mobile Radiation Shield | 042-519, 042-522 |

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 |

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. 133 Rev. E

Signature:



Biodex Medical Systems, Inc.

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