

BIODEX

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Shielded Dose Drawing System	PET Dose Drawing System	001-855, 007-984, 007-986 042-426, 042-449, 042-455 042-466, 042-467

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.

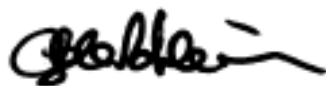
Company Representative: Clyde Schlein

Title: Vice President, Regulatory Affairs & Compliance

Date: May 1, 2019

No. 117 Rev. A

Signature:



Biodex Medical Systems, Inc.

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