BIODEX

DECLARATION OF CONFORMITY

PRODUCT INDENTIFICATION		
Type of Equipment	**Product Name(s)**	**Model/Number(s)**
Radiation Syringe Shields	Pro-Tec II	007-800, 007-801, 007-900, 007-901
	Pro-Tec III	007-723, 007-734, 007-735 007-736, 007-738, 007-755
	Pro-Tec IV	007-670, 007-675, 007-680, 007-685
	Beta	007-956, 007-957
	Dose Drawing	007-661, 007-663, 007-665 007-691, 007-693, 007-695
	Double-Ended PET Pig	001-793
	High Density Lead Glass	007-612, 007-620, 007-635, 007-652
	PET	007-969, 007-973, 007-975, 007-980, 007-983, 007-985, 007-990, 007-995
	PET/MR	007-961, 007-962, 007-966, 007-967
	PET Gaard Lock	007-711, 007-712, 007-713 007-716, 007-717, 007-718
	Z-PET	007-945
	Replacement Glass	007-974, 127-691, 127-693, 127-695 127-700, 127-734, 127-735, 127-738 127-789, 127-999
	Syringe Carrier	001-179, 001-180, 001-181, 001-182
	Syringe Recapper	008-300
Serial Number	N/A	

MANUFACTURER		
Name of Company	**Address**	**Representative**
Biodex Medical Systems, Inc.	20 Ramsey Road Shirley, NY 11967-4704 USA	Clyde Schlein *Vice President, Regulatory Affairs & Compliance*

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. 142 Rev. D

Signature: