BIODEX

DECLARATION OF CONFORMITY

PRODUCT INDENTIFICATION		
Type of Equipment	**Product Name(s)**	**Model/Number(s)**
Radionuclide Test Pattern	Bar Phantoms	243-800, 243-935, 243-955 243-985, 243-987
	Flood Phantom	043-054
	Thyroid Neck Phantom	043-365
	PET, NEMA 2012/IEC 2008	043-767
	PET, Flangeless, Esser	043-772
	Phantom Funnel	131-010
	Replacement Bottle	043-361
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. 098 Rev. O

Signature: