BIODEX

DECLARATION OF CONFORMITY

PRODUCT INDENTIFICATION		
Type of Equipment	**Product Name(s)**	**Model/Number(s)**
Powered Exercise Equipment	Mobility Assist	950-570
Serial Number	[ENTER]	

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 12	Annex VII of MDD 93/42/EEC Council Directive	EN 60601-1, 3rd Ed IEC 60601-1, 3rd Ed, clause 15.3.5 IEC 60601-1, 3rd Ed, clause 9.4 IEC 60601-1, 3rd Ed, clause 7.9 ISO 10535, clause 6 EN 60601-1-2:2014

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. 146 Rev. A

Signature: