

Biodex Medical Systems, Inc. 20 Ramsey Road, Shirley, New York, 11967-4704

## **DECLARATION OF CONFORMITY**

93/42/EEC as amended by
33/12/222 us umenaca sy
2007/47/EC : LVFS 2003:11
September 25, 2018
Powered Exercise Equipment
GAIT TRAINER 3 TREADMILL
950-400, 950-401, 950-402, 950-403, 950-404, 950-405, 950-406, 950-407, 950-408
SAMPLE
IEC/EN 60601-1: Ed 3 IEC 60601-1-2:2007 UL 60601-1:2003 Ed 1 Rev 2006 CAN/CSA C22.2 No.: 601-1-M90
I Measuring Annex V
INTERTEK SERVICES
0413
41312068-01 July 20, 2023

## BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM

ISO 13485:2003 Certificate #9060-5-03

## **ISSUED BY MANUFACTURER:**

Biodex Medical Systems, Inc.

20 Ramsey Road

Shirley, New York 11967-4704 USA

I, the undersigned, hereby declare that the equipment specified above conforms to the Directive(s) and Standard(s) as specified.

Stolle signature

Clyde Schlein Vice President, Regulatory Affairs & Compliance

## **<u>Authorized European Representative:</u>**

EC REP EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

#CD-CC-137 rev H