


BIODEX

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

DECLARATION OF CONFORMITY

APPLICATION OF COUNCIL DIRECTIVE(S) AND NATIONAL REGULATION OF SWEDEN	93/42/EEC as amended by 2007/47/EC : LVFS 2003:11
DATE OF ISSUE	November 28, 2017
TYPE OF EQUIPMENT	Powered Exercise Equipment
BRANDNAME	GAIT TRAINER 3 TREADMILL
MODEL NUMBER(s)	950-400, 950-401, 950-402, 950-403, 950-404, 950-405, 950-406, 950-407, 950-408
SERIAL NUMBER	SAMPLE
STANDARD(s) TO WHICH CONFORMITY IS DECLARED	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
CLASS	I Measuring Annex V
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES
CE IDENTIFICATION #	0413 
3BE.C. Certificate # & Expiration Date	41312068 July 20, 2018
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM ISO 9001:2008 Certificate #98-1091h-03 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.	



BUBB *signature*
0BClyde Schlein
Vice President,
Regulatory Affairs & Compliance
1B
V

Authorized European Representative:



#CD-CC-137 rev G