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	**May 1, 2018**
TYPE OF EQUIPMENT	Powered Exercise Equipment
BRANDNAME	Mobility Assist
MODEL NUMBER(s)	950-570
SERIAL NUMBER	**SAMPLE**
STANDARD(s) TO WHICH CONFORMITY IS DECLARED	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
CLASS	I Annex VII, Rule 12
CE IDENTIFICATION	CE
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES
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.	

signature

Clyde Schlein
Vice President,
Regulatory Affairs & Compliance

Authorized European Representative

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