


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	Partial Body Weight Support Training
BRANDNAME	Unweighing System, NxStep
MODEL NUMBER(s)	945-480, 950-485
SERIAL NUMBER	SAMPLE
STANDARD(s) TO WHICH CONFORMITY IS DECLARED	IEC 60601-1 IEC 60601-1 clause 15.3.5 IEC 60601-1 3 rd Ed, clause 9.4 IEC 60601-1 3 rd Ed, clause 7.9 ISO 10535 clause 6 EN 60601-1-2
CLASS	I Annex VII, Rule 12
CE IDENTIFICATION #	
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES
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.	



signature

Clyde Schlein
Vice President,
Regulatory Affairs & Compliance

Authorized European Representative



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