


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	Force Measuring Platform
BRANDNAME	Balance System SD
MODEL NUMBER(s)	950-440, 950-441, 950-444
SERIAL NUMBER	SAMPLE
STANDARD(s) TO WHICH UNIT CONFORMITY IS DECLARED	IEC/EN 60601-1 Ed 3 IEC 60601-1-2:2007 Ed 3 UL 60601-1:2003 Ed 1 Rev 2006 CAN/CSA C22.2 601-1-M90
CLASS	I Measuring Annex V
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES
CE IDENTIFICATION #	0413 
E.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.	

Authorized European Representative



signature

Clyde Schlein
Vice President, Regulatory Affairs & Compliance



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