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

DECLARATION OF CONFORMITY

APPLICATOIN 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	BioSway
MODEL NUMBER(s)	950-460, 950-461
SERIAL NUMBER	**SAMPLE**
STANDARD(s) TO WHICH UNIT CONFORMITY IS DECLARED	EN 60601-1-2:2007 IEC 601-1:1988+A1:1991+A2:1995 UL 60601-1, 1st Ed., 04/25/2003 CAN/CSA C22.2 No.:601-1-M90 (R2005)
CLASS	I Measuring Annex V
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM ISO 9001:2008 CERTIFICATE #98-1091h-03 ISO 13485:2003 CERTIFICATE #9060-5-03	

The BioSway is manufactured in compliance to the product's specifications and meets the above referenced Standards.

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.

Clyde Schlein
Vice President,
Regulatory Affairs & Compliance

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