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 29, 2017**
TYPE OF EQUIPMENT	Upgrade Bundle converts Biodex System 3 to Biodex System 4
BRANDNAME	Biodex
MODEL NUMBER(s)	850-830 Components of 840-000, 850-000
SERIAL NUMBER	**SAMPLE**
STANDARD(s) TO WHICH UNIT CONFORMITY IS DECLARED	IEC 60601-1-2: 2001 2ND Edition, Rev. 2 EN 60601-1: (1990) A1+A2+A11+A12+A13 (1996) EN 60601-1-1: 2000 IEC 60601-1-4: 2000 Ed 1.1
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM ISO 9001:2008 CERTIFICATE #98-1091h-03 ISO 13485:2003 CERTIFICATE #9060-5-03	
CLASS	II a Annex II
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES

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

CD-CC-111.1-comp rev D