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	**September 26, 2018**
TYPE OF EQUIPMENT	Biodex System 3
BRANDNAME	Biodex
MODEL NUMBER(s)	830-000, 830-002, 830-201, 830-202, 830-204, 830-205, 830-206, 830-207, 830-208 835-000, 835-002, 835-201, 835-202, 835-205, 835-206, 835-207, 835-208
SERIAL NUMBER	**SAMPLE**
STANDARD(s) TO WHICH UNIT CONFORMITY IS DECLARED	EN 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 13485:2003 CERTIFICATE #9060-5-03	
CLASS	II a Annex II
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES
E.C. CERTIFICATE #	41313009

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-030 rev R