

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	June 4, 2018
TYPE OF EQUIPMENT	Isokinetic Testing and Evaluation System Attachments
BRANDNAME	System 4 Attachments
MODEL NUMBER(S)	<u>Pediatric Attachments:</u> 821-321 Attachment, Shoulder, Pediatric 830-316 Attachment, Hip, Pediatric 830-474 Attachment, Left Knee, Pediatric 830-475 Attachment, Right Knee, Pediatric
SERIAL NUMBER	SAMPLE
CLASS	I Annex VII
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM 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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#CD-CC-147