

# BIODEX

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

## DECLARATION OF CONFORMITY

<b>APPLICATION OF COUNCIL DIRECTIVE(S) AND NATIONAL REGULATION OF SWEDEN</b>	93/42/EEC as amended by 2007/47/EC : LVFS 2003:11
<b>DATE OF ISSUE</b>	November 28, 2017
<b>TYPE OF EQUIPMENT</b>	Isokinetic Testing and Evaluation System Attachments
<b>BRANDNAME</b>	UE Hemiparetic Attachments
<b>MODEL NUMBER(s)</b>	830-540
<b>BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM</b> ISO 9001:2008 CERTIFICATE #98-1091h-03 ISO 13485:2003 CERTIFICATE #9060-5-03	
<b>CLASS</b>	I Annex VII
<b>QUALITY SYSTEM REGISTRAR</b>	INTERTEK SERVICES
<b>ISSUED BY MANUFACTURER:</b> 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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