


BIODEX

Biodes 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	December 22, 2016	
TYPE OF EQUIPMENT	Isokinetic Testing and Evaluation System	
BRANDNAME	System 4	
MODEL NUMBER(s) 850-000 System 4 Pro includes: 850-000-E300 Dell CPU 850-109-J800 Software C07-015 Biodes Advantage Software Manual C08-051 Biodes Multi Joint System Installation Instructions C08-246 System 4 Multi Joint System Poster C14113 HP Office Jet printer C12940 Touch Screen Monitor 900-860 Power head / Gimbal 830-000-K904 Limb Support Kit: 830-154 Arm / Leg Support 830-155 Foot Rest Tube 820-153 Small Tee Cap Screws (14 pieces) 945-300-M322 Levelers (6 pieces) 850-000-K900 PRO Attachments Kit: 830-157 Elbow / Shoulder Attachment 830-158 Wrist Attachment 830-174 Left Knee Attachment 830-175 Right Knee Attachment 830-321 Shoulder Attachment 830-332 Ankle Attachment 830-350 Calibration Weight 830-315 Complete Hip Attachment 830-320-A000 Seat Back Brace Assembly 830-240 Attachment Rack 850-230-A000 Universal Pro Single Chair Assembly 850-145-A000 Tee Base 835-210-A000 CDS Cart	840-000 System 4 Quick Set includes: 850-000-E300 Dell CPU 840-109-J800 Software C07-015 Biodes Advantage Software Manual C08-051 Biodes Multi Joint System Installation Instructions C08-246 System 4 Multi Joint System Poster C14113 HP Office Jet printer C12940 Touch Screen Monitor 900-860 Power head / Gimbal 830-000-K904 Limb Support Kit: 830-154 Arm / Leg Support 830-155 Foot Rest Tube 820-153 Small Tee Cap Screws (14 pieces) 945-300-M322 Levelers (6 pieces) 840-000-K900 Quick Set Attachments Kit: 830-157 Elbow / Shoulder Attachment 830-158 Wrist Attachment 830-174 Left Knee Attachment 830-175 Right Knee Attachment 830-321 Shoulder Attachment 830-332 Ankle Attachment 830-350 Calibration Weight 830-240 Attachment Rack 835-135-A000 Quick Set Single Chair Assembly 840-140-A000 Tee Base 835-210-A000 CDS Cart	852-000 System 4 MVP includes: 850-000-E300 Dell CPU 840-109-J800 Software C07-015 Biodes Advantage Software Manual C08-051 Biodes Multi Joint System Installation Instructions C08-246 System 4 Multi Joint System Poster C14113 HP Office Jet printer C12940 Touch Screen Monitor 900-860 Power head / Gimbal 830-000-K904 Limb Support Kit: 830-154 Arm / Leg Support 830-155 Foot Rest Tube 820-153 Small Tee Cap Screws (14 pieces) 945-300-M322 Levelers (6 pieces) 840-000-K900 Quick Set Attachments Kit: 830-157 Elbow / Shoulder Attachment 830-158 Wrist Attachment 830-174 Left Knee Attachment 830-175 Right Knee Attachment 830-321 Shoulder Attachment 830-332 Ankle Attachment 830-350 Calibration Weight 830-240 Attachment Rack 832-135-A000 MVP Single Chair assembly 852-145-A000 Tee Base 835-210-A000 CDS Cart
SERIAL NUMBER ON UNIT	SAMPLE	
STANDARD(s) TO WHICH UNIT CONFORMITY IS DECLARED	EN 60601-1, 3 rd Ed EN 60601-1-2: 2007	
CLASS	II a Annex II	
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES	
CE IDENTIFICATION #	0413 	

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E.C. Certificate # & Expiration Date	41313009 July 20, 2018
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM	
ISO 9001:2008 CERTIFICATE #98-1091h-03 ISO 13485:2003 CERTIFICATE #9060-5-03	
ISSUED BY MANUFACTURER:	
Biodex Medical Systems, Inc. 20 Ramsay 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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Molenstraat 15
2513 BH, The Hague
The Netherlands

CD-CC-111 rev J