

# BIODEX

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

## DECLARATION OF CONFORMITY

<b>DATE OF ISSUE</b>	<b>November 28, 2017</b>
<b>TYPE OF EQUIPMENT</b>	Ultrasound Tables, AC Powered
<b>BRANDNAME &amp; MODEL NUMBER(s)</b>	<b>Echo Pro Echocardiography Table</b> 058-700, 058-705 <b>Echo/Vasc Pro Vascular</b> 058-702, 058-707 <b>Econo Echocardiography Table</b> 058-701, 058-706 <b>Econo Ultrasound Table</b> 058-726, 058-727 <b>Sound Pro Combination Table</b> 058-710, 058-715 <b>Ultra Pro Ultrasound Table</b> 058-720, 058-725 <b>Vasc Pro Vascular Ultrasound Table</b> 058-732, 058-733
<b>SERIAL NUMBER</b>	<b>SAMPLE</b>
<b>BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM</b>	ISO 9001:2008 CERTIFICATE #98-1091h-03 ISO 13485:2003 CERTIFICATE #9060-5-03
<b>STANDARD(s) TO WHICH CONFORMITY IS DECLARED</b>	EN 60601-1, 2 <sup>nd</sup> Ed, 1990+A1+A2 EN 60601-1: 1998 EN 61000-6-1 EN 61000-6-2 EN 61000-6-3 EN 61000-6-4 EN 60601-1-2 EN 1970 UL 60601-1, 1 <sup>st</sup> Ed, 2003/4/25 rev 2006/05/26 CAN/CSA C22.2 No.:601.1M9, 1990/01/11 (R2005)
<b>CLASS</b>	I Annex VII
<b>QUALITY SYSTEM REGISTRAR</b>	INTERTEK SERVICES
The Ultrasound Tables, AC Powered, are manufactured in compliance to the product's specifications and meets the above referenced Standards.	

**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-139