

# 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>	<b>November 28, 2017</b>			
<b>TYPE OF EQUIPMENT</b>	Personnel Radiation Shield			
<b>BRANDNAME(S) &amp; MODEL NUMBER(S)</b>	<b>Deluxe L-Block Shield</b> 042-413 <b>Compact L-Block with Dose Calibrator Shield</b> 042-433 <b>L-Block Shields</b> 042-419, 042-449  <b>L-Block Caves &amp; Accessories</b> 042-417, 042-425, 042-426, 042-434, 042-435			
<b>TYPE OF EQUIPMENT</b>	Personnel Radiation Shield			
<b>BRANDNAME(S) &amp; MODEL NUMBER(S)</b>	<b>Tabletop Shield</b> 042-224, 042-710  <b>Tabletop Shield Accessories</b> 042-226, 042-227, 042-228			
<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>AUTHORIZED EUROPEAN REPRESENTATIVE</b>	<table border="1"> <tr> <td style="text-align: center; vertical-align: middle;"><b>EC</b></td> <td style="text-align: center; vertical-align: middle;"><b>REP</b></td> <td><b>EMERGO EUROPE</b> Prinsessegracht 20 2514 AP The Hague The Netherlands</td> </tr> </table>	<b>EC</b>	<b>REP</b>	<b>EMERGO EUROPE</b> Prinsessegracht 20 2514 AP The Hague The Netherlands
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**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-124 rev E