

**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>September 25, 2018</b>		
<b>TYPE OF EQUIPMENT</b>	Radiation Shielded Containers		
<b>BRANDNAME MODEL NUMBER(s)</b>	Sharps Container Shield 039-325, 039-326, 039-330, 039-335, 039-350, 039-412		
<b>BRANDNAME MODEL NUMBER(s)</b>	Syringe Holder 009-205		
<b>BRANDNAME MODEL NUMBER(s)</b>	Shielded Containers 039-106, 039-110, 039-287, 039-288, 039-289, 050-200, 050-205, 050-250		
<b>TYPE OF EQUIPMENT BRANDNAME MODEL NUMBER(s)</b>	Syringe Recapper Recapper 008-300		
<b>BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM</b> 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" style="margin-left: auto; margin-right: auto;"> <tr> <td style="text-align: center; width: 40px; height: 40px;"><b>EC</b></td> <td style="text-align: center; width: 40px; height: 40px;"><b>REP</b></td> </tr> </table> <p><b>EMERGO EUROPE</b>                  Prinsessegracht 20                  2514 AP The Hague                  The Netherlands</p>	<b>EC</b>	<b>REP</b>
<b>EC</b>	<b>REP</b>		

**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-128 rev A