

**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>March 22, 2017</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 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" style="width: 100%;"> <tr> <td style="text-align: center; width: 50px;"><b>EC</b></td> <td style="text-align: center; width: 50px;"><b>REP</b></td> <td style="padding-left: 10px;"> <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 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

#CD-CC-128 rev A