

# 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>	Shielded Dose Drawing System			
<b>BRANDNAME</b>	PET Dose Drawing System			
<b>MODEL NUMBER(s)</b>	001-855 042-426 007-984 042-449 007-986 042-455 042-466 042-467			
<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><b>EC</b></td><td><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-117