

# 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>	<b>RADIATION SYRINGE SHIELDS</b>
<b>BRANDNAME</b> <b>MODEL NUMBER(S)</b>	<b>PRO-TEC II:</b> 007-800, 007-801, 007-900, 007-901 <b>PRO-TEC III:</b> 007-723, 007-734, 007-735 007-736, 007-738, 007-755 <b>PRO-TEC IV:</b> 007-670, 007-675, 007-680, 007-685 <b>BETA:</b> 007-956, 007-957 <b>DOSE DRAWING:</b> 007-661, 007-663, 007-665 007-691, 007-693, 007-695 <b>DOUBLE-ENDED PET PIG:</b> 001-793 <b>HIGH DENSITY LEAD GLASS:</b> 007-612, 007-620, 007-635, 007-652 <b>PET:</b> 007-973, 007-975, 007-980, 007-983, 007-985, 007-990, 007-995 <b>PET/MR:</b> 007-961, 007-962, 007-966, 007-967 <b>PET GAARD LOCK:</b> 007-711, 007-712, 007-713 007-716, 007-717, 007-718 <b>Z-PET:</b> 007-945 <b>REPLACEMENT GLASS:</b> 007-974, 127-691, 127-693, 127-695, 127-700 127-734, 127-735, 127-738, 127-789, 127-999
<b>TYPE OF EQUIPMENT</b> <b>BRANDNAME</b> <b>MODEL NUMBER(S)</b>	<b>SYRINGE CARRIER</b>  Biodex 001-179, 001-180, 001-181, 001-182
<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

**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*

**Authorized European Representative:**



**EMERGO EUROPE**  
Prinsessegracht 20  
2514 AP The Hague  
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**Clyde Schlein,**  
**Vice President, Regulatory Affairs & Compliance**

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