

BIODEX

Biodex Medical Systems, Inc.
20 Ramsey Road, Shirley, New York, 11967-4704

DECLARATION OF CONFORMITY

DATE OF ISSUE	September 25, 2018			
TYPE OF EQUIPMENT	Radiation Decontamination Kit			
BRANDNAME	Decontamination Kit			
MODEL NUMBER(s)	121-180			
BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM	ISO 13485:2003 Certificate #9060-5-03			
CLASS	I Annex VII			
QUALITY SYSTEM REGISTRAR	INTERTEK SERVICES			
EUROPEAN AUTHORIZED REPRESENTATIVE	<table border="1"><tr><td>EC</td><td>REP</td><td>EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands</td></tr></table>	EC	REP	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
EC	REP	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands		
<p>I, the undersigned, hereby declare the Decon Kit is assembled in compliance with the product's specifications. The respirator mask itself does not have an actual expiration date. There are components of the mask that can be, and are recommended, to be changed periodically based on the type and duration of usage (i.e., inhalation and exhalation valves). An unopened filter cartridge also would not have an expiration date, but should be changed/replaced periodically based on the usage.</p> <p>ISSUED BY MANUFACTURER: Biodex Medical Systems, Inc. 20 Ramsey Road Shirley, New York 11967-4704 USA</p>				



signature

Clyde Schlein
Vice President, Regulatory Affairs & Compliance

#CD-CC-122